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Occupational therapy intervention development, for individuals with a diagnosis of psychosis living in the community, to improve participation in activities of everyday life: a feasibility study for a pragmatic randomised controlled trial.

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Occupational therapy intervention development, for individuals with a diagnosis of psychosis living in the community, to improve participation in activities of everyday life: a feasibility study for a pragmatic randomised controlled trial.

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At no time during the registration for the degree of Doctor of Philosophy has the author been registered for any other University award without prior agreement of the Graduate Sub-Committee.

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Abstract

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Occupational therapy intervention development, for individuals with a diagnosis of psychosis living in the community, to improve participation in activities of everyday life: a feasibility study for a pragmatic randomised controlled trial.

Background: Having a diagnosis of schizophrenia is associated with employment difficulties, high mortality rates, substantial family burden and impoverished quality of life and it costs between 1.5 to 3 per cent of the total expenditure on national health care (Knapp et al 2004). However social functioning and participation can have a protective impact on mental health of people with a diagnosis of psychosis (Stain et al 2013).

Method: A systematic and phased approach to complex intervention development was undertaken involving: (1) A systematic review of effectiveness and (2) a feasibility study, designed to explore and test the key uncertainties of an effectiveness study, was conducted in two phases. This involved the development of an occupational therapy intervention specification and a feasibility study for a pragmatic randomised controlled trial (RCT). It utilised the *Developing and evaluating complex interventions guidelines (MRC 2008)*. A task analysis approach was applied to extrapolate occupational therapy theory, practice and outcomes for the intervention specification (Gitlin 2013). The feasibility study was carried out across two centres. It used the intervention specification and included both study and process outcomes. The primary outcome was participation in activities of everyday life and the secondary outcomes were health-related quality of life and self-reported experience of

occupational performance and satisfaction with occupational performance. Service user and carer involvement was integrated into the method.

Results: The systematic review highlighted that there was no evidence of effectiveness for individualised client-centred occupational therapy interventions on participation in activities of everyday life or quality of life/ health related quality of life. The methodological quality of the effectiveness studies was generally low and details provided regarding interventions made replication difficult. The feasibility study recruited less people *(n=20)* than planned *(n=64).* However the outcomes of self-reported experience of occupational performance *(p=.002)* and satisfaction with occupational performance *(p=.001)* and self-evaluated transition (SET) *(p=.026)* improved with occupational therapy and were found to be statistically significant *(p<.05).* The intervention specification captured 98% of occupational therapy provided and was shown to have good utility for research and practice purposes.

Conclusion: An intervention specification that reflects practice and has utility has been developed. Methods of measuring fidelity and adherence of occupational therapy have been designed and tested. Knowledge about how occupational therapy enables participation has advanced. The essential preparatory work to address the previously key uncertainties in a pragmatic RCT has been completed and the foundations for the next stage — a larger pragmatic RCT — have been put in place.

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Abbreviations

CMHT – Community mental health team

COPM – Canadian Occupational Performance Measure

COT - College of Occupational Therapy

CReDECI – Criteria for reporting the development and evaluation of complex interventions in healthcare

HoNOS – Health of the Nation Outcome Scale

ICF – International classification of functioning, disability and health

NICE – National Institute for Health and Care Excellence

PRECIS – pragmatic-explanatory continuum indicator summary

P-Scale- Participation Scale

RCT – Randomised controlled trial

SF-36 – The Short Form – 36 Health Survey

TIDieR – Template for intervention description and replication

TUS – Time Use Survey

USER-P – Utrecht Scale for Evaluation of Rehabilitation Participation

Chapter 1 Introduction

1.1 Introduction

A diagnosis of psychosis can have costs to the individual, their family and society. This study is concerned with the participation of people with a diagnosis of psychosis in their own life situation, as an indicator of health and recovery. Participation is a key component of the *International Classification of Functioning, Disability and Health (ICF)* (WHO 2001) and is synonymous with health; it is therefore an important outcome to aim for when working with people with a diagnosis of psychosis on their recovery. Occupational therapy theory postulates that it enables people to improve their functioning and access to opportunities for participation (Creek 2003). Whilst there is some evidence for a relationship between what people do and their health, there have been calls for this relationship to be tested and researched in the field of mental health (Creek and Hughes 2008). This thesis uses the Medical Research Council (MRC) (2008) guidelines, to report the robust research undertaken to prepare for a pragmatic randomised controlled trial (RCT) in the future; which would test the effectiveness of occupational therapy, to enable individuals with a diagnosis of psychosis, to increase their participation in their own life situation.

This chapter introduces psychosis as a general term for a class of disorders (see Section 1.2), defining how a diagnosis of psychosis is classified from a medical perspective and described from a psychological perspective (see Section 1.2.1). It discusses some of the impacts that having a diagnosis of psychosis can have on the individual, their families, carers and wider society (see Section 1.2.2), including the impact on their occupations and participation in the activities of their daily life (see Section 1.2.3).

The concept of participation as a meaningful outcome is presented and discussed in Section 1.3, including:

- The link to health, as indicated by participation being a core component of the *ICF* (WHO 2001) (see Section 1.3.1)
- Its relationship to health care policy (see Section 1.3.2) in the UK
- The foundational belief that participation is an important outcome of occupational therapy, that needs testing under research conditions (see Section 1.3.3)
- The challenges with measuring the concept of participation (see Section 1.3.4)

Current policy and practice guidelines for providing treatment for people with a diagnosis of psychosis, who live in the community are identified and outlined in Section 1.4. These are put in the context of mental health effectiveness research in general (see Section 1.5). Prior to the commencement of this thesis the evidence-base for occupational therapy and mental health and specifically with people with a diagnosis of psychosis was broadly scoped. The intention being to get an overview about what the evidence base regarding the effectiveness was at that point in time, to form foundations for the thesis. This also clarified and confirmed the drivers for the thesis. This introductory chapter presents and discusses the output of the initial scoping exercise regarding the evidence-base for occupational therapy, mental health in Section 1.6, including:

- Evidence of occupational therapy efficiency in mental health (see Section 1.6.1)
- Occupational therapy effectiveness research with individuals with a diagnosis of psychosis (see Section 1.6.2)

- Occupational therapy practice-driven evidence (see Section 1.6.3)
- Occupational therapy as a complex intervention and its relationship to carrying out effectiveness studies (see Section 1.6.4)

Furthermore there was a systematic review (see Chapter two), which took a robust and systematic approach to examining the research effectiveness base specifically focussed on the effectiveness questions of this thesis.

The potential link between advances in complex intervention research methodology and the ability to carry out more robust exploratory studies in occupational therapy, with people with a diagnosis of psychosis is discussed in Section 1.6.4. On overview is given regarding the advances in researching complex interventions methodology in Section 1.7. Including how the complex intervention frameworks have become more sophisticated, as the learning from effectiveness studies has triggered developments and updates in international guidelines.

Implementation science is introduced in Section 1.7.2, including the understanding of the importance of incorporating this consideration at the beginning of any effectiveness study. How this was approached in this study is explained.

The overall aim of the thesis is stated in Section 1.8 and in Section 1.9 an overview of the thesis structure is given.

1.2 Psychosis

1.2.1 Diagnosis of psychosis

Psychosis is a general term for a class of disorders, which includes the following descriptions; schizophrenia, schizoaffective disorder, schizophreniform disorder, delusional disorder and affective psychosis e.g. bipolar disorder or unipolar psychotic depression (National Institute for Health and Care Excellence (NICE) 2014a). The experience of psychosis is described by the British Psychological Society Division of Clinical Psychology:

> 'The experiences include hearing voices ('hallucinations'), believing things that others find strange ('delusions'), speaking in a way that others find hard to follow ('thought disorder') and experiencing periods of confusion where you appear out of touch with reality ('acute psychosis')' (Cooke 2014, p.10).

1.2.2 Impacts of a diagnosis of psychosis

It is estimated that one person in every hundred receives a diagnosis of schizophrenia in the UK, which equates to around 500,000 people and a similar number receive a diagnosis of bipolar disorder (Cooke 2014). It has been recommended that decision-makers recognise the breadth of economic impacts of a diagnosis of schizophrenia, well beyond health and including the societal costs (Mangalore and Knapp 2007).

> 'There are significant consequences of having a diagnosis of schizophrenia, for individuals, their families and the wider society; employment difficulties are very common, mortality rates are high, substantial family burden has been reported and impoverished quality of life often accompany the illness' (Knapp et al 2004, p.290).

The impact of treating people who have a diagnosis of schizophrenia on the health care budget is substantial. In an international literature review into the 'Costs of having schizophrenia' which drew the majority of the studies from

Europe and North America, it was estimated at typically costing between 1.5 per cent and 3 per cent of total national health care expenditures (Knapp et al 2004, p.290).

Having more evidence about what treatment interventions are most effective, at enabling people who have a diagnosis of schizophrenia or psychosis to recover, could potentially bring down the costs to the individuals, their families, the wider society, and the health service. There is a need to understand more about what enables people with a diagnosis of psychosis to participate; this study will focus on understanding more about how occupational therapy enables people with a diagnosis of psychosis to participate in activities of daily living, in their own communities.

1.2.3 Impact of a diagnosis of psychosis on occupations and participation in activities of everyday life

There have been a number of studies that have specifically explored and tried to quantify the impact of having a diagnosis of psychosis on the occupations and participation of individual's activities of everyday life. The areas of both activity and participation have been identified as being affected by having a diagnosis of psychosis or schizophrenia (Krupa et al 2010, Tenorio-Martinez et al 2009). In a study carried out in Mexico the ICF checklist was used to measure the incapacity experienced by people with a diagnosis of schizophrenia, anxiety and depression, the results indicated that people with a diagnosis of psychosis were more seriously incapacitated (Tenorio-Martinez et al 2009). A contrasting approach to understanding the ways that early psychosis affects occupational performance, was shown in a study, using a

phenomenological life history approach; eight themes were found clustered around three phases (Brown 2011):

- The historical context of their experiences (a seed unfolding)
- The detailed experiences of their acute episode (psychosis in full bloom)
- The meaning made of these experiences for the future (growing beyond psychosis)

Within the phase of 'psychosis in full bloom' a negative impact was described:

'With the onset of acute illness, lives became increasingly narrow in terms of the occupations, relationships, places frequented, and range of emotions experienced '(Brown 2011, p.158).

Increased social isolation and difficulties in work and education were also identified in a study which explored the perception of community functioning in young adults with recent-onset psychosis (Roy et al 2009). The young adults reported more handicap-creating situations than competence situations.

Recognising that a diagnosis of psychosis impacts peoples activities in daily living, 'time use' has been used to try to quantify this impact (Leufstadius and Eklund 2008, Berjerholm et al 2006). A study was carried out with 103 participants with persistent mental illness to investigate associations between time use in daily activities and sociodemographic and clinical factors (Leufstadius and Eklund 2008). It found that individuals with a diagnosis of psychosis spent less total time in daily activities than individuals with non-psychosis. It concluded that having a diagnosis of psychosis and high levels of general symptoms together explained most of the risk of having low total time use in activity (Leufsatdius and Eklund 2008).

1.3 Participation as a meaningful outcome

It's apparent that participation in everyday life and activities is often negatively affected by having a diagnosis of psychosis (see Section 1.2.3). In the second national survey of psychosis into the social cost of psychosis, it reported evidence that social functioning and participation have a protective impact on mental health (Stain et al 2013). It recommended that these are addressed for people with a diagnosis of psychosis (Stain et al 2013).

1.3.1 Participation and health

When people are healthy, they live their own lives with little or no input from health services. Participating in the activities and occupations of their daily lives is described in *the International Classification of Functioning, Disability and Health (ICF) (*WHO 2001) as one of the core components of health and health-related states. The *ICF* (2001) is a framework for the descriptions of health and health-related states and permits a common language for communication about health, across the world and in various disciplines and sciences (WHO 2001, p.3). The *ICF* (2001) is a multipurpose classification system, providing a scientific basis for understanding and studying health and health-related states, outcomes and determinants (WHO 2001, p.5). It is complementary to the *International Classification of Diseases; Tenth Revision (ICD-10),* which classifies health conditions (e.g. diseases, disorders and injuries); used in conjunction gives a greater understanding of the individual in the context of their overall health and well-being (WHO 2001). This relationship is complex and multi-faceted and involves an appreciation of how an individual's health condition interacts with who they are, their participation in their particular life context, and consequently their quality of life. This understanding importantly

helps to comprehend more about the facets involved in an individual's recovery. Personal recovery has been defined as a way of living a satisfying, hopeful and contributing life even with the limitations caused by illness (Anthony 1993). Subsequently participation as a core component of the *ICF* (WHO 2001) is a valid and important outcome to achieve with people with a diagnosis of recovery.

1.3.2 Participation and health care policy

A cross-Government strategy in the United Kingdom has recognised that there is *No health without mental health* and sets out a mental health outcomes strategy for people of all ages (Department of Health 2011). This paper recognised that good mental health and wellbeing is more than the absence of mental illness and identified that such benefits can include:

- More participation in community life
- Improved productivity
- Greater educational achievement
- Improved overall functioning

And more recently the *Five Year Forward View* for the National Health Service (NHS) in England, sets out how the health service needs to change; particularly having a more engaging relationship with patients, carers and citizens to promote wellbeing and prevent ill-health (NHS England 2014). This more engaging relationship is described as having four key components (p.1):

- Getting serious about prevention
- Empowering patients
- Engaging communities

- The NHS as a social movement

The *Five Year Forward View* also recognises that mental illness is the single largest cause of disability in the UK and has the ambition to achieve genuine parity of esteem between physical and mental health by 2020 (NHS England 2014).

1.3.3 Occupational therapy foundational beliefs: occupational therapy enables participation in activities of daily life

The foundational beliefs of occupational therapy are based on the principles of occupation and participation, and the importance of these to the health and well-being of the individual and society (Baum 2003, Law 2002, Vessby and Kjellberg 2010). An important understanding is that two people with the same disease can have different levels of functioning, and two people with the same level of functioning do not necessarily have the same health condition (WHO 2001, p.4). Occupational therapists are experts at assessing and understanding an individuals' level of functioning (Creek 2003). This is achieved through assessing, exploring, and coming to a shared understanding of the interaction between the individual, their occupations and their environments (Law et al 1996) and consequently their overall health and well-being. A rigorous literature review on the effects of occupation on health found that there was a wide range of research exploring the relationship between occupation and health, and limited knowledge about the ways in which occupation influences health (Creek and Hughes 2008). It was found that some studies put forward hypotheses about why health improvements occurred and that more research is needed to test these hypotheses (Creek and Hughes 2008, p.464-465).

1.3.4 Measuring participation

A particular issue with the concept of 'participation' is the way that it is presented in the *ICF* (WHO 2001) is often confused with activities, it is not well defined and conceptual clarity is lacking (Khetani and Coster 2007). It is difficult to research the concept of 'participation' without a clear definition about what it is. Operationalizing the term 'participation' from the *ICF* (2001) has international significance to health and health services. The WHO (2001) calls for more operationalization of the *ICF* (2001) to explore its practical utility; however to date it has not been widely researched in relation to mental health.

Therefore a systematic literature review and concept analysis was used to develop a definition for this study focussed on mental health. The definition created and utilised in this thesis was: 'Participation occurs when an individual is involved in activities, within the context of their life, which provides that person with a sense of engagement'.

1.4 Policy and practice guidance

This thesis is set in community mental health. Occupational therapists are established members of the multidisciplinary team in community mental health. This is defined in the *Policy implementation guidelines* (DoH 2001, DoH 2002) and in the *Standards for adult community mental health services* (Royal College of Psychiatrists (RCPsych 2016). One of the standards for adult community mental health teams is that service users have access to occupational therapy (RCPsych 2016). Box 1.1 shows the key components expected from community mental health teams to support service users with their basic daily living.

Basics of daily living

- For those with severe and enduring illness, the care plan should include areas of particular vulnerability and identify strategies to address them
- Help in accessing local opportunities in work and education – Users should be encouraged to seek occupation where possible
- Recommends MDT approach and 1-1.5 Occupational therapists per 350 service users and a staffing and skill mix to deliver the interventions listed

Box 1.1 Daily living as a key component of CMHTs, *CMHT Policy Implementation Guidelines,* DoH 2002, p.13

Basic daily living is also identified as a key component in Assertive outreach services, as demonstrated in Box 1.2.

Basics of daily living

- Care plan should address all aspects of daily living
- Empowering service users and respecting their independence
- Daily living skills training to raise independence of service user
- Help in accessing local services and educational, training and employment opportunities
- A pathway to education and valued employment can be mapped and help in achieving this.
- Recommends MDT approach to deliver all interventions listed and occupational therapists to be part of the MDT

Box 1.2 Daily living as a key component of Assertive Outreach, *Policy Implementation Guidelines*, DoH 2001, p.30

National Institute for Health Care Excellence (NICE), guidelines

The *Psychosis and schizophrenia in adults, prevention and management, National Institute for Health and Care Excellence (NICE) guidelines* (NICE 2014b) make recommendations about evidence based treatment for this client group. The guidelines recommend that occupational and educational aspects are part of the assessment and care planning process, occupational interventions are provided and that impairment and functioning is monitored (NICE 2014b). However the guidance does not specify who would provide this. The guidelines do state:

> 'For people who are unable to attend mainstream education, training or work, facilitate alternative educational or occupational activities according to their individual needs and capacity to engage with such activities, with

> the ultimate goal of returning to mainstream education, training or employment' (NICE 2014b, p.19).

The Bipolar disorder: assessment and management guidelines (NICE 2014c) have less detail about this client groups occupational, and everyday activities of daily living needs and treatment. However the guidance does say:

> 'Offer supported employment programmes to people with bipolar disorder in primary or secondary care who wish to find or return to work. Consider other occupational or educational activities, including pre-vocational training for people who are unable to work or unsuccessful in finding employment' (NICE 2014c, p.31).

1.5 Mental Health effectiveness research

The randomised controlled trial (RCT) is the most robust study design with which to investigate the effectiveness of health treatments (Hotopf et al 1999, p.222). There has been dissatisfaction with the number and quality of trials of psychosocial interventions in mental health, relative to those of drug therapy and there are claims that they have had insufficient impact on everyday clinical practice (Green 2006, p.268). One suggestion to support improvement is that the same rigour applied to efficacy trials in psychiatry, now needs to be applied to effectiveness trials (Tansella et al 2006).

1.6 Occupational therapy evidence based practice

1.6.1 Evidence of occupational therapy efficiency in mental health

There continues to be a call for more effectiveness studies in occupational therapy (Lin 2013, Bannigan et al 2008) and in occupational therapy, as applied to mental health (College of Occupational Therapists 2006).

Two systematic reviews considered the evidence of occupational therapy efficiency generally (Steultjens et al 2005) and specifically to mental health

(Banningan and Spring 2012). Table 1.1 summarises the systematic reviews that were identified as relevant to this study. The systematic review that was conducted regarding the efficiency of occupational therapy, with different clinical conditions from reviewing published systematic reviews, gave an overview of the evidence for effectiveness for occupational therapy (Steultjens et al 2005). It concluded that the effectiveness of occupational therapy for people with mental health problems was unknown due to insufficient evidence and recommended that the sparse effectiveness research is addressed in future research (Steultjens et al 2005). Futhermore Bannigan and Spring (2012) carried out a rigorous literature search for systematic reviews in occupational therapy and mental health and found four reviews, only two of which were focussed on the effectiveness of interventions. These two reviews were occupation-focussed; however they did not refer directly to occupational therapy in the titles or abstracts, no conclusions were drawn about the effectiveness of occupational therapy. Subsequently the state of the evidence base specifically for the effectiveness of occupational therapy with people with a diagnosis of psychosis from systematic reviews is explored further and discussed in Section 1.6.2.

1.6.2 Occupational therapy effectiveness research with individuals with a diagnosis of psychosis

A scoping exercise for understanding of the effectiveness research of occupational therapy with individuals with a diagnosis of psychosis was undertaken at the beginning of the study. This focussed on identifying the relevant systematic reviews in this area of occupational therapy practice, with the aim of establishing an overview of the current state of the effectiveness

evidence-base. This process identified seven related systematic reviews, which are summarised in Table 1.1.

Reference	Focus of systematic review
Steultjens et al (2005)	Occupational therapy with different physical and mental health conditions
Banningan and Spring (2012)	Occupational therapy in mental health
Gibson et al (2011)	Occupational therapy interventions (recovery of community integration and normative life roles) for people with a serious mental illness
Arbesman and Lodgeson (2011)	Occupational therapy interventions (employment and education) for people with a serious mental illness
Bullock and Bannigan (2011)	Activity based group work with people with severe and enduring mental illness
Tungpunkom et al (2012)	Life skills programmes for individuals with chronic mental illness
Lynman et al (2014)	Skill building for people with serious mental illness

Table 1.1 A summary of the relevant systematic reviews

The effectiveness of occupational therapy with individuals with a diagnosis of psychosis was reviewed in three studies (Arbesman and Lodgeson 2011, Bullock and Bannigan 2011, Gibson et al 2011) and two systematic reviews were related to occupational therapy practice with this client group (Lynman et al 2014, Tungpunkom et al 2012).

Two occupational therapy systematic reviews were conducted about adults with serious mental illness. They evaluated the effectiveness of interventions within 'occupational therapy's scope of practice' related to recovery in the areas of community integration and normative life roles (Gibson et al 2011) and employment and education (Arbesman and Logsdon 2011). Whilst these studies included people with a diagnosis of psychosis, they also included studies of participants with diagnosis of a non-psychotic nature and there was

no separate sub-group analysis by diagnosis. Therefore specific generalization about the effectiveness of occupational therapy with people with a diagnosis of psychosis was not possible on the basis of these systematic reviews. Bullock and Bannigan (2011) reviewed the effectiveness evidence in the area of activity-based group work for people with severe and enduring mental illness and wasn't specific to a diagnosis of psychosis and therefore no conclusions could be drawn for this study.

Two systematic reviews were related to occupational therapy practice and not specific to occupational therapy or subject to separate sub-group analysis of occupational therapy. These were a Cochrane systematic review of life skills programmes for individuals with chronic mental illness (Tungpunkom et al 2012) and a systematic review of skill building, for people with serious mental illness (Lyman et al 2014). Conversely generalisation of the results could not be made for this study because occupational therapy interventions were not analysed independently within the reviews.

Participation in everyday activities is a key outcome for occupational therapy, as discussed in Section 1.3. Unfortunately the evidence of the effects of occupational therapy on participation was also not reviewed specifically for people with a diagnosis of psychosis in any of the systematic reviews identified. The outcome of this scoping exercise informed the aim of the systematic review conducted for this thesis. The systematic review is reported in Chapter two. This evaluated the effectiveness of occupational therapy in improving participation in activities of everyday life for adults with a diagnosis of psychosis.

1.6.3 Occupational therapy practice driven evidence

I as well as being the researcher was also an occupational therapy professional lead in adult mental health services. The interest and a driver to conduct these studies came from my experiences in that role. I undertook that role in the context of the policy and practice guidelines that have already been outlined in Section 1.4 and the limited amount of effectiveness studies in this area of occupational therapy see Section 1.6. Occupational therapy is an established therapy in mental health services (DoH 2001, DoH 2002, RCPsych 2016) and systems and processes for occupational therapy practice are clearly outlined in the NHS organisation that I work. Part of those systems and processes include the routine use and collation of occupational therapy outcomes from standardised occupational therapy outcome measures. These are integral to practice and used to guide and evaluate individual service user's progress from the engagement with occupational therapy. The use of the Canadian Occupational Performance Measure (COPM) was regularly showing positive changes in individual's perceived occupational performance and satisfaction with their occupational performance post occupational therapy, in community mental health settings. This was a driver to exploring and developing this study, to test the effectiveness of occupational therapy in a robust research setting.

1.6.4 Occupational therapy as a complex intervention

The lack of effectiveness studies in this area of occupational therapy may be partially due to the complexity of occupational therapy (discussed later in this section) and the associated challenges of carrying out effectiveness studies with such complexity. Occupational Therapy has been defined as a complex intervention, through a commissioned piece of work from the College of

Occupational Therapists (Creek 2003). Further to this discussion Box 1.3 shows some of the dimensions of what makes an intervention complex for effectiveness research purposes, as described by the Medical Research Council (MRC 2008). The first dimension is that the intervention could contain several interacting components (MRC 2008). This depiction is synonymous with an occupational therapy description:

'Occupational therapy comprises' of a number of separate elements which seem essential to the proper functioning of the intervention although the "active ingredient" of the intervention that is effective is difficult to specify' (Creek 2003, p.14).

- Number of and interactions between components within the experimental and control interventions
- Number and difficulty of behaviours required by those delivering or receiving the intervention
- Number of groups or organisational levels targeted by the intervention
- Number and variability of outcomes
- Degree of flexibility or tailoring of the intervention permitted

Box 1.3 Some dimensions of complex interventions (Medical Research Council 2008, p.7)

Another dimension of complexity in occupational therapy is the degree of flexibility or tailoring of the intervention permitted (MRC 2008). This was found in a study by Hitch et al (2013), who carried out a metasynthesis of lived experience in the engagement in activities and occupations, by people who had experience psychosis and it concluded the importance of tailoring occupational therapy:

'Tailoring therapy to each client's needs, enabling opportunities for pleasurable engagement and the valuing of intrinsically motivating occupations should be priorities for occupational therapists working with people who have experienced psychosis' (Hitch et al 2013, p.84-85).

Describing occupational therapy for research effectiveness purposes

Cook and Birrell (2007) developed an Occupational therapy intervention schedule for people with psychotic conditions in community settings, using the delphi method with mental health occupational therapists in a NHS Trust. This was followed by secondly using a nominal group technique with occupational therapists at a national conference (Cook and Birrell 2007). *Occupational therapy as a complex intervention* (Creek 2003) was integrated into this piece of work. The Occupational therapy intervention schedule created was made up of 82 component parts. It was piloted in a RCT about the effectiveness of occupational therapy for people with psychotic conditions in the community (Cook et al 2009). The major limitation of the study was reported as contamination of the experimental intervention between the intervention and control groups, i.e. some participants in the treatment as usual group received occupational therapy. This may have been partially in relation how the intervention schedule was described, whilst a landmark in its time the scope was very wide. The control group received some of the 88 components; however it was not completely clear whether this constituted a full and complete occupational therapy intervention. Since this time, developing and evaluating complex intervention research methodology has progressed (MRC 2008, Richards and Hallberg 2015). This has offered more opportunities to refine and test occupational therapy as a complex intervention in effectiveness studies.

1.7 Methodology for researching complex interventions

1.7.1 Methodology for researching complex interventions has advanced

Randomised controlled trial (RCT) methodology has been perfected largely through drug trials, whereas occupational therapy typically involves complexities

that are not present in drug trials (Nelson and Mathiowetz 2004). Frameworks and guidance for designing and evaluating complex interventions to improve health have been advanced (Campbell et al 2000, MRC 2008, Richards and Hallberg 2015). The guidance aims to help researchers choose appropriate methods for evaluating the impact of complex interventions (MRC 2008).

Best practice requires complex interventions to be developed systematically starting with each of the key uncertainties in the design (MRC 2008, Richards 2015). The main elements of the development-evaluation-implementation process of complex interventions are: developing an intervention; piloting and feasibility; evaluating the intervention; implementation and reporting at each stage (MRC 2008). The aim of this study was considered in relation to this guidance to ensure that the most appropriate research method was applied. This process begins by identifying the relevant, existing evidence base, ideally through carrying out a systematic review (MRC 2008).

1.7.2 Implementation Science

'We should differentiate here between dissemination – the communication of information to others – and implementation – the embedding of new interventions into routine health or social care systems and activities' (Richards 2015, p.13).

It is important to incorporate considerations about implementation early on in the development and evaluation phase of a complex intervention (MRC 2008). These are considered in Chapter four as part of developing and intervention specification for occupational therapy. Implementation is a highly active process which uses strategies to integrate evidence-based health interventions into practice (Richards 2015). Therefore the application of implementation science will also be revisited in the final discussion Chapter seven.

1.8 Overall aim of the thesis

This thesis is part of a series of studies that form a systematic approach to developing and evaluating occupational therapy as a complex intervention, with individuals with a diagnosis of psychosis and its feasibility, within a pragmatic randomised controlled trial (RCT) (MRC 2008).

Aim

To develop and evaluate an occupational therapy intervention for individuals with a diagnosis of psychosis, living in the community, to improve their participation in activities of everyday life and carry out a feasibility study for its use in a pragmatic RCT.

1.9 Structure of the thesis

This thesis is presented in a further six chapters. Chapter two reports on the systematic review of the evidence base for occupational therapy with people with a diagnosis of psychosis living in the community. It was carried out as recommended by MRC (2008) as an important foundation for developing and evaluating occupational therapy as a complex intervention in this area. A protocol was developed using consistent guidance from Khan et al (2001) (see Section 2.3.1). This was then published on the international systematic database called PROSPERO (Inman et al 2015) (see Appendix 1). In Section 2.4.2 a quality assessment is applied to all the identified relevant studies. Due to the lack of homogeneity between studies a best evidence synthesis (see Section 2.3.8) is utilised to synthesise the data (Steultjens et al 2002). Conclusions are drawn about the evidence of effectiveness in Section 2.6,

including effectiveness studies would ideally focus on to be able to answer the question of the systematic review in the future.

Chapter three, methodology, incorporates the lessons learned from the systematic review. It discusses the philosophical assumptions from which the thesis was considered and then delineates the thesis objectives in Section 3.1. The study design is debated and outlined in Section 3.2. The study method follows on in Section 3.3; which takes a carefully phased approach to exploring and testing the key uncertainties of an effectiveness study of occupational therapy with people with a diagnosis of psychosis, living in the community; as recommended by the MRC (2008). Service user and carer involvement is defined in Section 3.3.1 and the four principles of biomedical ethics are introduced in Section 3.3.2, these are utilised to consider the ethical issues of the feasibility study throughout the chapter (Beauchamp and Childress 2009). The methodology discusses and delineates a feasibility study for a future pragmatic RCT in this area of practice, together with an associated study protocol (in Appendix 13) (see Section 3.4). The feasibility study method is reported primarily using the *CONSORT 2010 Statement* (Schulz et al 2010) and the *Improving the reporting of pragmatic trials: an extension of the CONSORT statement* (Zwarenstein et al 2008). As it was a feasibility study, it includes both study outcomes and measures, and process outcomes and associated data collection tools (see Section 3.4.4). The optimum sample size and enrolment are discussed and outlined in Section 3.5. The data collection processes are presented in Section 3.6 and data security is dealt with in Section 3.7. The approach to data analysis for both the study and process outcomes is discussed and described in Section 3.8.

Chapter four reports the first phase of the study method which was the development of an occupational therapy intervention specification, through applying developing and evaluating complex interventions methodology. This has been likened to ‘unravelling the black box’ (Sermeus 2015, p.112). This development process incorporated the learning from Chapter two, the systematic review. Including the generally low methodological quality and the intervention descriptions being insufficient to enable replicability within the effectiveness studies in this area of practice (see Section 2.6). It utilises guidance to ensure that the reporting of the development of the occupational therapy intervention is a transparent process (Mohler et al 2012). Processes to develop the occupational therapy intervention specification are critiqued (see Section 4.3) and the approach taken is discussed and delineated in Section 4.4; the findings are then presented in Section 4.5, which include:

- What the occupational therapy intervention consists of and how it links to theory and outcomes (see Section 4.5.1)
- How it will be operationalised (see Section 4.5.2)
- How it will be delivered in practice (see Section 4.5.3)

Chapter five present the findings of the study outcomes from the feasibility study together with the details about what the intervention provided actually was (Section 5.2.3). This includes the actual process of assessing fidelity and adherence (Section 5.2.3.9). The extent of the fidelity and adherence to the delivery of the intervention as planned is also reported (see Section 5.2.3.10). Details about what other (non-occupational therapy) interventions were received by the participants in the study are given (see Section 5.2.4). The numbers used for the analysis are stated (see Section 5.2.5). The outcomes and

estimation of effect are presented (see Section 5.2.6) and the occupational therapists rating of effectiveness are summarised (see Section 5.2.7).

Chapter six presents the findings related to the process outcomes from the feasibility study. It deals largely with qualitative data from the occupational therapist focus groups (see Section 3.6.8) which has been analysed using a content analysis approach (Elo and Kyngas 2007). Data is also triangulated from other sources and includes quantitative analysis to enhance the picture given and to strengthen the validity of the findings. It presents the findings about how occupational therapy enables people with a diagnosis of psychosis to participate in activities of daily life (see Section 6.3). This also includes the enablers and facilitators (see Section 6.3.4) and what the hurdles and hinders were (see Section 6.3.5) to participation in daily life are; from the perspective of participants and occupational therapists. The process outcomes related to doing occupational therapy research in practice are presented in Section 6.4. The last findings of this chapter concern the utility of the outcome measures and process (see Section 6.5).

The discussion in Chapter seven interprets the findings from the feasibility study, including the application of the intervention specification within it. It considers the findings in the context of the evidence base at the beginning of the thesis and how the knowledge base has been extended through the thesis. The study outcomes from the feasibility study are discussed, including the primary and secondary outcomes and ratings of occupational therapy effectiveness from participants and the occupational therapists perspective (see Section 7.2). The study sample size, recruitment process and characteristics of the participants are explored and areas for further development are identified (see Section 7.3). The method of measuring participation in activities of daily

living is reviewed and critiqued (see Section 7.4). The validity of the description of occupational therapy; that is the occupational therapy intervention specification is considered, including its utility for a RCT (see Section 7.5). The process outcomes regarding the methods for measuring fidelity (see Section 7.6) and adherence (see Section 7.7) are explored. Within the context of the level of reporting in the research studies in the systematic review (Chapter two) and acknowledging the systems and processes set up through this study that has enabled measurement. The triangulation of data regarding how occupational therapy enables participation in activities of everyday life is discussed (see Section 7.8). The main limitations and implications are brought together in Section 7.9 and the challenges and lessons learned are discussed (see Section 7.10). The contribution to the occupational therapy research and practice knowledge base is articulated (see Section 7.11). The thesis is summed up regarding how it has set the foundations for an occupational therapy pragmatic RCT with people with a diagnosis of psychosis, living in the community and recommendations for future research (see Section 7.12).

Chapter 2 Systematic review

2.1 Introduction

The aim of this thesis was to develop and evaluate an occupational therapy intervention for individuals with a diagnosis of psychosis, living in the community, to improve their participation in activities of everyday life and carry out a feasibility study for its use in a pragmatic RCT. An important foundation for developing and evaluating complex interventions is to identify the relevant, existing evidence base, ideally by carrying out a systematic review (MRC 2008).

'…systematic reviews aim to be systematic in the identification and evaluation of included literature, objective in their interpretation of this, and have reproducible conclusions' (Bowling 2009, p.147).

Literature was searched for relevant systematic reviews over the past 10 years and there were no recent systematic reviews directly relevant to the focus of this study; therefore a systematic review (MRC 2008) was carried out. This chapter explicates the rationale for this systematic review by setting it firstly in the context of key systematic reviews in occupational therapy and mental health, and secondly specifically to occupational therapy with people with a diagnosis of psychosis (see Section 2.2). It provides an explicit statement of the question that the review set out to answer in Section 2.2.1.

It is good practice to create and publish a systematic review protocol on a register such as the international prospective register for systematic review protocols (PROSPERO) (Shamseer et al 2015). The systematic review protocol was developed and published on PROSPERO (PROSPERO 2015:CRD42015026706) and can be found in Appendix 1. The protocol was developed using the *Preferred Reporting Items for Systematic Review and Meta-Analysis protocols (PRISMA-P) 2015 statement* (Moher et al 2015).

From Section 2.3 the methods for the systematic review and the reasoning for choosing the eligibility criteria are debated and defined, including: the population (see Section 2.3.1.1), the intervention (see Section 2.3.1.2), the outcomes (see Section 2.3.1.3) and the study designs (see Section 2.3.1.4). The information sources are defined in Section 2.3.2 and the development of the search strategy is discussed and then outlined in Section 2.3.3. The management of the study records are presented in Section 2.3.4, together with how the data was extracted (see Section 2.3.5) and the outcomes prioritised (see Section 2.3.6). The process for assessing the methodological quality is discussed and described (see Section 2.3.7) and the rationale for the application of a data synthesis method is given together with the process utilised in Section 2.3.8.

The results are presented in Section 2.4; which includes details of the studies selected (see Section 2.4.1), outcome of the methodological quality assessment (see Section 2.4.2), characteristics of the included studies (see Section 2.4.3), details of the occupational therapy interventions (see Section 2.4.4), and analysis of the outcome data regarding the effectiveness of occupational therapy with the pre-defined systematic review outcomes (see Section 2.4.5).

The overall outcomes of the review are discussed in Section 2.5 and in Section 2.6 conclusions regarding the evidence for the level of effectiveness of occupational therapy are made. Finally recommendations are made about how the evidence base can be strengthened within future occupational therapy effectiveness studies in this area. These recommendations are then incorporated into the methodology in Chapter three.

2.2 Background and rationale

The literature search for relevant systematic reviews of occupational therapy and people with a diagnosis of psychosis identified seven related systematic reviews, which are summarised in Table 2.1.

Key
Level I – Systematic reviews, meta-analysis, randomised controlled trials
Level II – Two groups, nonrandomised studies (e.g., cohort, case-control)
Level III – One group, nonrandomised (e.g. before and after, pretest and posttest)
RCT – Randomised controlled trial

Reference	Objectives of review	Designs included	Methods of analyses
Steultjens et al (2005)	Overview of the available systematic reviews of the efficacy of occupational therapy and implications for practice and research.	Systematic review (16)	Search (1966-October 2004) Conclusions from reviews that assessed and incorporated methodological quality in synthesis of data - assumed as more valid than those that were unclear.
Banningan and Spring (2012)	To identify the systematic reviews conducted about occupational therapy in mental health.	Systematic review (2)	Search (dates not stated)
Gibson et al (2011)	Effectiveness of interventions within occupational therapy's scope of practice; that focus on recovery of community integration and normative life roles for adults with a serious mental illness.	Level I (31) Level II (13) Level III (8)	Search (Studies from 1990 – end date not stated) Methodological quality assessed Categories analysed separately Stated that a 'Critically Appraised Topic' was used to summarise and synthesise
Arbesman and Lodgeson (2011)	Effectiveness of interventions within occupational therapy's scope of practice; that focus on participation and performance in occupations related to paid and unpaid employment for people with serious mental illness.	Level I (37) Level II (5) Level III (4)	Search (Studies from 1990 – end date not stated) Methodological quality assessed Categories analysed separately Stated that a 'Critically Appraised Topic' was used to summarise and synthesise

Table 2.1 Relevant systematic reviews, descriptive overview

Bullock and Bannigan (2011)	Effectiveness of activity-based group work in helping people with severe and enduring mental illness in community settings to improve their functional ability and/ or reduce their mental health symptoms.	RCT (3)	Search (Dates varied for different journals, inclusive of 1800-March 2009) Methodological quality assessed Narrative synthesis
Tungpunkom et al (2012)	Effectiveness of life skills programmes compared with standard care or other comparable therapies for people with chronic mental health problems.	RCT (7)	Search (June 2010 – update of previous Cochrane review dated 1998) Methodological quality assessed Data synthesis – random-effects method
Lynman et al (2014)	Skill building for people with serious mental illness	Systematic reviews & meta-analysis (18)	Search (1995 – March 2013) Methodological quality assessed Level of evidence – effectiveness combined with methodological quality rating

Table 2.1 Relevant systematic reviews, descriptive overview (continued)

Two systematic reviews considered the evidence of occupational therapy efficiency in mental health generally (see Section 2.2.1). The efficiency of occupational therapy with individuals with a diagnosis of psychosis was reviewed in three systematic reviews and two systematic reviews were related to occupational therapy practice with this client group (see Section 2.2.2).

2.2.1 Evidence of occupational therapy efficiency in mental health generally

Steultjens et al (2005) carried out a systematic review of the efficiency of occupational therapy with different clinical conditions in published systematic reviews, giving an overview of the evidence for effectiveness. It concluded that the effectiveness of occupational therapy with patients with mental health problems was unknown due to insufficient evidence and recommended that the sparse efficacy research is addressed in future research (Steultjens et al 2005).

Futhermore Bannigan and Spring (2012) carried out a rigorous literature search for systematic reviews in occupational therapy and mental health and found four reviews, only two of which were focussed on the effectiveness of interventions. These two reviews were occupation-focussed; however they did not refer directly to occupational therapy in the titles or abstracts, no conclusions were drawn about the effectiveness of occupational therapy.

2.2.2 Evidence of occupational therapy efficiency with individuals with a diagnosis of psychosis

Two occupational therapy systematic reviews were carried out for adults with serious mental illness evaluating the effectiveness of interventions within 'occupational therapy's scope of practice' related to recovery in the areas of community integration and normative life roles (Gibson et al 2011) and employment and education (Arbesman and Logsdon 2011). Whilst these studies included people with a diagnosis of psychosis, they also included studies of participants with diagnosis of a non-psychotic nature and there was no separate sub-group analysis by diagnosis; therefore specific generalization about the effectiveness of occupational therapy with people with a diagnosis of psychosis was not possible for the basis of this study. Bullock and Bannigan (2011) reviewed the effectiveness evidence in the area of activity-based group work for people with severe and enduring mental illness; again there was no separate sub-group analysis for people with a diagnosis of psychosis.

Two systematic reviews were related to occupational therapy practice and not specific to occupational therapy or subject to separate sub-group analysis of occupational therapy. These were a Cochrane systematic review of life skills programmes for individuals with chronic mental illness (Tungpunkom et al 2012)

and a systematic review of skill building, for people with serious mental illness (Lyman et al 2014). Conversely generalisation of the results could not be made for this study.

Participation in everyday activities is a key outcome for occupational therapy, as discussed in the introductory chapter (see Section 1.3) and the evidence of the effects of occupational therapy on participation was also not reviewed specifically for people with a diagnosis of psychosis in any of the systematic reviews identified in Section 2.2.2. Therefore the aim of this systematic review was to evaluate the effectiveness of occupational therapy at improving participation in activities of everyday life for adults with a diagnosis of psychosis.

2.2.3 Systematic review question

Does occupational therapy improve participation in activities of everyday life for adults with a diagnosis of psychosis?

2.3 Methods

2.3.1 Eligibility criteria

The eligibility criteria were developed using guidance on how to frame structured questions for systematic reviews in Khan et al (2011), this was used though out this process to ensure consistency. The question components include: the populations; the interventions; the outcomes and the study designs (Khan et al 2011). Each component is articulated in turn, together with the rationale for selection.

2.3.1.1 The population

The criteria to fulfil when describing the population for a systematic review has been defined as:

'A succinct description of a group of participants, their clinical problem and the health care setting' (Khan et al 2011, p.9).

This includes the condition being studied and the domain/ problem; Table 2.2 describes the full inclusion and exclusion criteria for the population. NICE (2014) guidance was used to extrapolate how the diagnosis of psychosis was described. Co-morbidity of physical ill health and dual diagnosis can occur with people with a diagnosis of psychosis and were included, as long as the primary diagnosis was psychosis. The criteria to identify occupational need and/ or impairment and/or disability that indicated referral to occupational therapy was replicated from a systematic review of occupational therapy for community dwelling elderly people (Steultjens et al 2004). As the study was to be based in adult mental health services, the focus of this review was on people who were 18 years and over. No upper age limits were defined as some adult mental health services in the UK now include older adults. Diagnoses based on organic causes were excluded to keep the primary focus on psychotic diagnosis.

Consideration was given to defining the context of the health care setting. For example: community, acute inpatients, residential rehabilitation or supported accommodation. However preliminary searches indicated limited effectiveness studies in this area and the context was unrefined, to enable knowledge about effectiveness to be reviewed in all contexts researched.

The condition and domain being studied
People with a diagnosis of psychosis and participation in activities of everyday life
The population **Inclusion** • Adults with a diagnosis of psychosis, including; schizophrenia, schizoaffective disorder, schizophreniform disorder, delusional disorder and affective psychosis e.g. bipolar disorder or unipolar psychotic depression (National Institute for Health and Care Excellence (NICE 2014) • Dual diagnosis where the diagnosis of psychosis is the primary diagnosis. • Co-morbidity of physical ill health where the diagnosis of psychosis is the primary diagnosis • Identified occupational need and/ or impairment and/or disability that indicated referral to occupational therapy (Steultjens et al 2004) **Exclusion** • Children aged below 18 years old • People with non-psychotic mental health disorder as the primary diagnosis • People with dual diagnosis where the non-psychotic illness is the primary diagnosis • Co-morbidity of physical ill health where the physical health diagnosis is the primary diagnosis • People with a diagnosis of an organic brain disorder or suspected organic cause to the psychosis

Table 2.2 The population

2.3.1.2 Intervention The intervention is the main action(s) being considered (Khan et al 2011). The intervention of occupational therapy is outlined in Table 2.3 followed by the comparators/ controls.

The intervention
The intervention is occupational therapy; occupational therapy practice is focused on enabling individuals to change aspects of their person, the occupation, the environment, or some combination of these to enhance occupational participation (WFOT 2012, p.15) Studies will be included when they investigate at least one of the following: a. Occupational therapy practice as defined by WFOT (2012) b. Occupational therapy designed to optimise participation in activities of everyday life Studies will be excluded when they primarily investigate: a. Individual Placement Support (IPS) b. Cognitive remediation c. Predictors of functioning/ recovery outcomes d. Cognitive behavioural therapy social skills/skills training not provided by an occupational therapist
Comparators/ controls
Different types of interventions; usual care or no intervention for comparative studies or no comparator for observational studies without control groups

Table 2.3 The intervention and comparators/ controls

Whilst defining the intervention of occupational therapy for this review, other descriptions of occupational therapy were considered from related occupational therapy systematic reviews (Steultjens et al 2004, Arbesman and Logsdon 2011, Gibson et al 2011). The *POSITION STATEMENT: Occupational therapy (2010)* (WFOT 2012) was used to derive a valid broad description of occupational therapy, that was specific enough to enable it to be used to assess the interventions within research studies as within the realm of occupational therapy or not. Preliminary searches highlighted that a number of related interventions that did not fit within the WFOT 2010 description of occupational therapy were identified, subsequently these were set as exclusion criteria (see Table 2.3).

The comparators/controls chosen (see Table 2.3) were recommended as appropriate for the types of study designs in this systematic review (Khan et al 2011).

2.3.1.3 The outcomes

The outcomes are the clinical changes in health state and other related changes that are expected as a result of the intervention. Identifying all the clinically relevant outcomes helps to examine the success or failure of the intervention (Khan et al 2011). The specified outcomes for the review can be found in Box 2.1. The first two primary outcomes are derived from *The POSITION STATEMENT: Occupational therapy (2010)* (WFOT 2012) to synchronise with the intervention description and also include functional ability, which is sometimes used to describe occupational performance (Bowling 2005). Time use was also included as this has been used as an indicator of participation for people with a diagnosis of schizophrenia (Harvey et al 2006). No limiters were set with regards to outcome measure tools of the primary or secondary outcomes because preliminary searches had indicated no consensus on utilisation of outcome measures.

The secondary outcomes of quality of life and health-related quality of life were chosen because participation and activities are part of the *International Classification of Functioning, Disability and Health (ICF)* (WHO 2001), which describes health and health-related states. Therefore they were anticipated to be a secondary outcome to changes in participation in activities of everyday life.

Primary outcomes

Participation in activities of everyday life is the primary outcome; studies must measure at least one of the primary or secondary outcomes (outlined below):

- Participation and satisfaction with activities of everyday life
- Occupational performance in activities of daily living (includes self-care, productivity and leisure) or functional ability
- Time use in activities

Secondary outcomes

- Quality of life and health-related quality of life

No limiters set for the outcome measures utilised to measure the primary or secondary outcomes

Box 2.1 The outcomes

2.3.1.4 The study designs

Preliminary searches carried out whilst developing the systematic review protocol indicated limited effectiveness studies in this area, as previously identified (Bannigan and Spring 2012, Steultjens et al 2005). Where there is a dearth of randomised controlled studies it can become necessary to consider other designs (Khan et al 2011). Steultjens et al (2002) and Steultjens et al (2004) addressed this issue by including efficacy studies, which were either a randomised controlled trial (RCT) or a controlled clinical trial (CCT) or other design (OD), acknowledging that these designs can guide future research. The study designs included in this review are outlined in Box 2.2, as described in Khan et al 2011).

- Randomised controlled trial (with concealed allocation)
- Experimental study without randomisation (including quasi-experimental or quasi-randomised or pseudo-randomised studies)
- Observational study with control group; cohort study or case-control study
- Observational study without control groups; cross-sectional study; before-and-after study and case series

Box 2.2 The study designs

2.3.2 Information sources

Articles for the systematic review were derived from relevant information sources to answer the research question including databases, journals and systematic reviews. Databases searched individually were: AMED; CINAHL; Cochrane Library; EMBASE, MEDLINE; OT Seeker and PsychInfo from 1990 up to July 2015. Key journals were hand searched from 2005 to July 2015, as outlined in Box 2.3, with missing issues listed in Table 2.4.

American Journal of Occupational Therapy
Australian Occupational Therapy Journal
British Journal of Occupational Therapy
Canadian Journal of Occupational Therapy
OTJR, occupation, participation and health/ Occupational Therapy Journal of Research
Occupational Therapy in Mental Health
Occupational Therapy International
Scandinavian Journal of Occupational Therapy
Schizophrenia Bulletin
Schizophrenia Research

Box 2.3 Hand searched journals, January 2005 - July 2015

Journal title	**Dates of missing editions**	
British Journal of Occupational Therapy	Dec 2014	Jan-July 2015
Australian Journal of Occupational Therapy	Jan-Dec 2005	Jan-Aug 2006
Canadian Journal of Occupational Therapy	Jan-Dec 2005	
OTJR, occupation, participation and health	2004 fall (4)	
Scandinavian Journal of Occupational Therapy	2008, (2)	2009, (4)

Table 2.4 Journals missing after hand searching in three University Libraries

The reference lists of related systematic reviews were scanned for potentially eligible studies; Arbesman and Logsdon (2011); Lyman et al (2014); Gibson et al (2011) and Tungpunkom et al (2012). The reference lists of all studies selected for inclusion were scanned for potentially eligible studies.

2.3.3 Search strategy

The search strategy was developed based on the population and the intervention, stated in the systematic review question (see Section 2.3). The search terms were then checked against the MeSH (Medical Sub-Headings) of each database to ensure maximum sensitivity. Table 2.5 shows an example search strategy used for MEDLINE and CINAHL; search strategies used for all databases can be found in Appendix 2.

Databases	**Search terms, Set 1 (Diagnosis/problem)**	**Boolean terms**	**Search terms, Set 2 (Intervention)**
MEDLINE CINAHL	"Psychotic disorders" (Major subject heading) OR "Schizophrenia" (Major subject heading) OR "Bipolar disorder" (Major subject heading)	AND	"Occupational therapy" (Major subject heading) OR "Vocational rehabilitation" (Major subject heading) OR "Self care" (Major subject heading) OR "Leisure activities" (Major subject heading) OR "Activities of daily living" (Major subject heading) OR "Skills training" (Title) OR "Life skills" (Title).

Table 2.5 Example search strategy used for MEDLINE and CINAHL

The search strategy was piloted and informed the following decisions:

- Diagnosis was used to identify the population because occupational/ functional need was not always defined in studies and databases.
- Outcomes were not specified because pilot search strategies had shown that using them as search terms reduced the sensitivity of the search and the number of citations generated were unmanageable for this review.
- The study design was undefined because:

  'General databases have subject indexing for some study designs but this

alone may not be adequate for searching' (Khan et al 2011, p.29).

- English language restrictions were applied to all searches because it was beyond the scope of this study to do language translations.

2.3.4 Study records

2.3.4.1 Data management

The citation results from each database search were uploaded manually and stored securely on a discrete database for the systematic review; relevant full text articles were stored on the same database together with information about inclusion/ exclusion and data quality assessments.

2.3.4.2 Selection process

Two reviewers carried out the relevance checking independently by applying the pre-defined criteria for inclusion and exclusion to the titles and abstracts (see Appendix 3 for inclusion/ exclusion checklist); full manuscripts of all citations considered relevant by either reviewer were obtained (Khan et al 2011). Two reviewers independently examined the full texts of all the potentially relevant citations to see if the pre-defined criteria had been met or not; a list of excluded studies and the reason for exclusion were recorded (Khan et al 2011). Any disagreements were resolved through discussion between the two reviewers, although a third reviewer was available for consultation had no consensus been achieved.

2.3.4 Data collection process

Data was extracted by one reviewer and checked for completeness and accuracy by a second reviewer on a standardised data extraction form (see Appendix 4). The form was piloted before formal use in the review.

2.3.5 Data items

Data was extracted on the characteristics of the studies, that is the: number of participants; study method; inclusion/ exclusion criteria; intervention (experimental and control) and outcome measures, similar to data extracted by Steultjens et al (2002). The *Template for Intervention Description and Replication (TIDieR)* was used to guide extraction of specific data about the interventions, as this is designed to support effective reporting of interventions (Hoffman et al 2014). Whenever possible the mean (standard deviation) at baseline and the standardized mean difference with 95 percent confidence interval was collected for all relevant outcomes of effects (Steultjens et al 2002).

2.3.6 Outcomes and prioritization

The primary outcome (participation in activities of everyday life) and secondary outcomes (quality of life and health-related quality of life) that were listed in the question components of the systematic review in Box 2.1 formed the last part of the data extraction form (see Appendix 4).

2.3.7 Risk of bias

The risk of bias of all included studies was assessed independently by two reviewers. Disagreements were resolved by discussion; however if consensus had not been met a third reviewer would have made the decision. Risk of bias of included studies was assessed by replicating the assessment process utilised by Steultjens et al (2002) in a systematic review of occupational therapy for rheumatoid arthritis. The quality assessment consisted of 11 criteria for internal validity, six descriptive criteria and two statistical criteria. Three modifications were made to the specification of the criteria for the methodological quality items a., c., and j., in order for the specification to be valid for this review. All criteria were scored as yes, no or unclear. This list was

initially recommended by Van Tulder et al (1997) and includes criteria proposed by Jadad et al (1996) and Verhagen et al (1998). RCT and CCT studies were considered to be of high quality if at least six criteria for internal validity, three descriptive criteria, and one statistical criterion were scored positively (see Appendix 5). The methodological quality of the ODs was also assessed replicating the assessment process utilized by Steultjens et al (2002), who adapted a list created by Van Tulder et al (1997). The *methodological quality assessment* for ODs consisted of seven criteria for internal validity, four descriptive criteria, and two statistical criteria (see Appendix 6) and scored in the same manner. Studies were of sufficient quality if the criteria scored positively for: internal validity (four), descriptive (two) and statistical (one).

2.3.8 Data synthesis

2.3.8.1 Best evidence synthesis

Preliminary searches indicated that meta-analysis of quantitative data may not be possible due to the lack of homogeneity between studies. In a similar scenario Steultjens et al (2002) formulated a best-evidence synthesis based on one proposed by Van Tulder et al (2003). The best-evidence synthesis (see Illustration 2.1) was utilised in this review because it attributes levels of evidence to the effectiveness, taking account of the study design, the methodological quality, type of outcome measures and the statistical significance of the findings and includes performing a sensitivity analysis by excluding low quality studies (Steultjens et al 2002).

2.3.8.2 Planned summary measures, data handling and combining

Information from each of the studies was extracted and tabulated including information about the population, interventions, outcomes and effects found in each one of the studies and their confidence intervals (Khan et al 2011). The

information was collated and tabulated as per the four subgroup intervention categories (see Table 2.8).

Strong evidence	Provided by consistent, statistically significant findings in outcome measures in at least two high quality RCTs~
Moderate evidence	Provided by consistent, statistically significant findings in outcome measures in at least one high quality RCT and at least one low quality RCT or high quality CCT~
Limited evidence	Provided by statistically significant findings in outcome measures in at least one high quality RCT~, or provided by consistent, statistically significant findings in outcome measures in at least two high quality CCTs~ (in the absence of high quality RCTs)
Indicative findings	Provided by statistically significant findings in outcome and/or process measures in at least one high quality CCT or one low quality RCT~ (in the absence of high quality RCTs), or provided by consistent, statistically significant findings in outcome and/or process measures in at least two ODs with sufficient quality (in absence of RCTs and CCTs)~
No evidence	In cases of results of eligible studies that do not meet the criteria for one of the above-stated levels of evidence, or in case of conflicting results among RCTs and CCTs, or in case of no eligible studies
RTCs = randomised controlled trials; CCTs = controlled clinical trials; ODs = other designs.~ If the proportion of studies that show evidence is <50% of the total number of studies within the same category of methodological quality and study design (RCTs, CCTs or ODs), we state no evidence	

Illustration 2.1 Best evidence synthesis (permission granted to reproduce from Steultjens et al (2002)

2.3.8.3 Subgroup analysis

Analysis of the occupational therapy interventions was applied to comprehensive occupational therapy, i.e. occupational therapy practice that is focused on enabling individuals to change aspects of their person, the occupation, the environment, or some combination of these to enhance occupational participation (WFOT 2012). Also to occupational therapy interventions that focussed on interventions in one of these three aspects. Four intervention categories were created in total (see section 2.4.3). Analysis of the clinical setting subgroups (community, hospital and residential rehabilitation/

supported accommodation) was considered; however there was heterogeneity about how the occupational therapy interventions were provided in these settings, preventing this analysis from being valid.

2.4 Results

2.4.1 Selection of studies

The selection of studies are summarised in Illustration 2.2. After relevance checking by title and abstract, 110 articles were identified, 60 duplicate records were removed and 47 full articles were sourced (two dissertations and one study that was highlighted in conference proceedings could not be sourced).

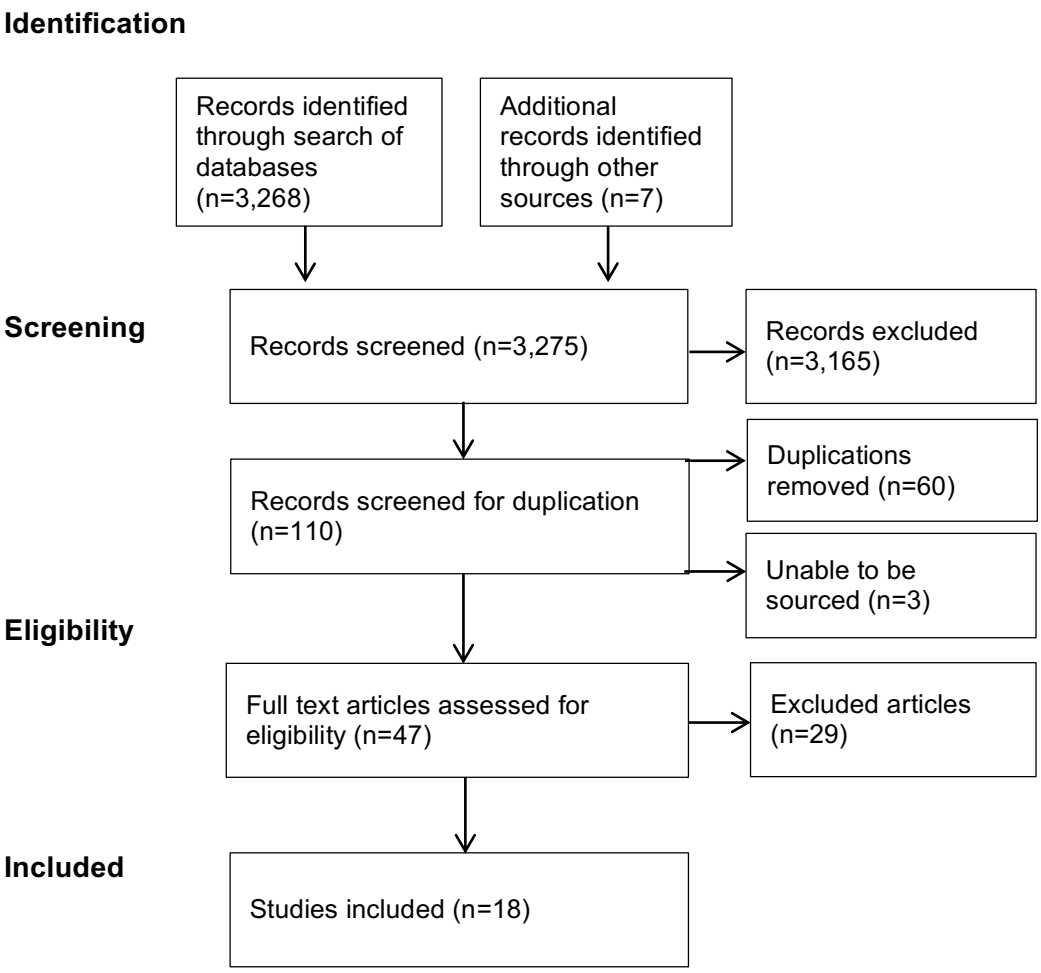

Illustration 2.2 PRISMA flow diagram

2.4.1.1 Excluded studies

Of the 47 full articles accessed, 29 were excluded as they did not meet the inclusion criteria for the systematic review (see Appendix 3); the reasons for exclusion are outlined in Table 2.6. The reasons for exclusion included: intervention not occupational therapy or not defined as occupational therapy as per the systematic review guidelines (see Table 2.2); participants had a diagnosis other than psychosis; outcomes measured were not included in systematic review guidelines (see Box 2.1); MDT intervention; included participants below 18 years old; psychological intervention and not an effectiveness study.

First author (reference)	Reason for exclusion
Anzai et al (2002)	Not occupational therapy
Bickes et al (2001)	Participants with schizophrenia, mood disorders and personality disorders
Champney and Dzurec (1992)	Participants with schizophrenia (42%) and other diagnosis not stated, not occupational therapy
Chuang et al (2005)	Not effectiveness study
Cook and Howe (2003)	Multi-disciplinary (MDT) primary care intervention
Creegan and Williams (1997)	Outcomes measured not included in review
Dean et al (2014)	Not occupational therapy
Foruzandeh and Parvin (2012)	Outcomes measured not included in review
Hayes et al (1995)	Not occupational therapy
Holzner et al (1998)	MDT rehabilitation intervention
Jao and Lu (1999)	Outcomes measured not included in review
Jin (1994)	Included participants aged from 16 years, not occupational therapy, outcome measures not included in review
Kopelowicz et al (1998)	MDT intervention, outcome measures not included in review
Kopelowicz et al (2006)	Outcomes measured not included in review

Table 2.6 Excluded studies and rationale

Major et al (2009)	Participants from 17years
Ojeda et al (2012)	Occupational therapy not specified as per review specification
Oka et al (2004)	Outcomes measured not included in review
Poon et al (2010)	Participants from 15years
Reisman et al (1991)	Not occupational therapy
Roldan-Merino et al (2013)	Not occupational therapy
Rouleau et al (2009)	MDT intervention
Salyers et al (2014)	Not occupational therapy
Sauter and Nevid (1991)	Psychological intervention
Schindler (2005)	Not specified as occupational therapy, provided by rehabilitation staff (profession not specified)
Schindler (1999)	Participants with diagnosis of schizophrenia and major affective disorder (actual diagnosis not specified).
Sachs et al (2012)	Occupational therapy stated as part of control (treatment as usual); occupational therapy not specified as per review specification
Tan (2009)	Participants with schizophrenia (84%) and other diagnosis not stated
Tatsumi et al (2011)	Outcomes measured not included in review
Vaccaro et al (1992)	MDT intervention

Table 2.6 Excluded studies and rationale (continued)

2.4.2 Methodological quality

The methodological quality of 18 studies (nine RCTs, five CCTs and four ODs) included in the review were assessed, i.e. outlined in Table 2.7. Two RCTs had high methodological quality and seven were rated as low quality. All CCT and OD studies were rated as having low methodological quality. The RCT and CCT studies reported on average four items of internal validity rather than the minimum of six to meet the quality criteria as described in Section 2.3.7. Method of randomisation, relevant outcome measures and comparable timings of outcome measures were reported by approximately two-thirds of the studies. All

other internal validity criteria were reported by less than a third of the studies. With regards to descriptive criteria all the RCT and CCT studies described short-term follow up measurement. With just over half of the studies explicitly describing the index and control interventions and all other descriptive criteria were reported by less than a third of the studies. The minimum statistical criterion was met by all the RCT, CCT and OD studies. All four OD studies reported on relevant outcome measures and short-term follow up measurement. Three studies had comparable timings of outcome measurement for all participants and all other criteria were reported by two studies or less.

First author (ref)	**Internal validity**	**Description**	**Statistical**	**Methodological quality**
RCTs				
Buchain et al (2003)	b1, n, p,	c, m1	o, q,	low
Chan et al (2007)	b1, j, l, n,	d, k, m1, m2	o,	low
Cook et al (2009)	b1, b2, f, i, j, l, n, p,	a, c, d, m1,	o, q,	high
Duncombe et al (2004)	b1, j, n,	d, m1,	o, q,	low
Edgelow and Krupa (2011)	b1, j, n,	m1,	o, q,	low
Grimm et al (2009)	b1, b2, e, h, i, j, n,	d, k, m1,	o, q,	high
Hadas-Lidor et al (2001)	b1, i, j, l, n, p,	m1, m2	o, q,	low
Liberman et al (1998)	b1, i, j, l, n,	m1, m2	o, q,	low
Tsang and Pearson (2001)	b1, i, j, n,	a, d, m1	o,	low
CCTs				
Hayes et al (1991)	b1, j, l, n, p,	d, m1,	o, q,	low
Hoshi et al (2013)	i, n,	c, d, m1	o, q,	low
Katz and Keren (2011)	j, n,	a, d, m1, m2,	o, q,	low
Raweh and Katz (1999)	j, n,	k, m1,	o, q,	low
Tanaka et al (2014)	j, n,	c, k, m1,	o, q,	low

Table 2.7 Characteristics and quality of included studies

ODs				
Brown et al (2002)	g, j, l,	m1,	o,	low
Lindstrom et al (2012)	j, l, n,	a, d, k, m1, m2,	o, q,	low
Mairs and Bradshaw (2004)	i, j, n,	a, d, m1,	o, q,	low
Odes et al (2011)	i, j, n,	k, m1, m2,	o, q,	low
Only the fulfilled criteria are reported High quality RCT or CCT = six internal validity, three descriptive and one statistical criterion Sufficient quality OD = four internal validity, two descriptive and one statistical criterion **See Appendix 5 and 6 for the Criteria for Methodological Quality Assessments*				

Table 2.7 Characteristics and quality of included studies (continued)

2.4.3 Characteristics of included studies

The characteristics of all the included studies (see Table 2.8) were grouped according to the experimental intervention into four categories:

- **Life skills training, as an occupational therapy intervention**

  This applied to one or a combination of remedial, compensatory, and educative approaches alongside occupational therapy theory to teach and develop life skills for independent living (Cordingley and Pell 2014). This was the largest category encompassing five RCTs and one OD.

- **Individualised client-centred occupational therapy interventions**

  Client-centred occupational therapy interventions have been described as being tailored from a program to meet participant's specific occupational needs (Gibson et al 2011). As all the research studies critiqued were delivered on a one-to-one basis this category was referred to as individualised client-centred occupational therapy interventions. This category included two RCTs, one CCT and two ODs.

- **Activity-based, occupational therapy group interventions**

  These combined the use of activity with the group setting to develop skills and/ or encourage social interaction (Bullock and Bannigan 2011). This category contained one RCT and three CCTs.

- **Cognitive occupational therapy interventions**

  Cognitive occupational therapy interventions are underpinned by a combination of the cognitive behavioural frame of reference and occupational therapy models of practice to improve occupational performance or functional ability (Lee and West 2014). This was the smallest category with one RCT, one CCT and one OD.

Characteristics of included randomised controlled trial (RCT), controlled clinical trial (CCT) and other design (OD)*.

(E = experimental group, C = control group, TAU = treatment as usual)

*All outcomes relevant to the systematic review are underlined

Authors (ref.)	N	Methods	Inclusion criteria/ setting	Intervention	Outcome measures
Life skills training, as an occupational therapy intervention					
Brown et al (2002)	43	OD	Schizophrenia or schizoaffective disorder. Community, USA	Life skills training: Grocery shopping intervention	Test of grocery shopping skills
Chan et al (2007)	81	RCT	18-65 years, schizophrenia or schizoaffective disorder (DSM-IV), stable mental condition, primary education or above. Inpatient, psychiatric male admission ward, China	E: Illness management: Transforming Relapse and Instilling Prosperity (TRIP) C: Ward Occupational Therapy	Scale of Unawareness of Mental Disorder, SF-36, readmission rates
Duncombe et al (2004)	44	RCT	Non paranoid schizophrenia or schizoaffective disorder for > five years, negative symptoms of schizophrenia. Home or clinic, USA	E1: Cooking skills training at home E2: Cooking skills training at clinic	The Allen Cognitive Level Screen (ACLS), Kitchen Task Assessment (KTA-M)
Grimm et al (2009)	8	RCT	Receiving hospital treatment > 6 months, diagnosed as subtype of schizophrenia or schizoaffective disorder, ability to comprehend English. Hospital, USA	E: Cooking skills training C: Cooking skills training (TAU)	Performance of self-care skills (PASS)

Table 2.8 The characteristics of all the included studies

Liberman et al (1998)	84	RCT	Persistent and unremitting forms of schizophrenia. Outpatients, USA	E: Skills training: U.C.L.A. Social and Independent Living Skills Program C: Psycho-social Occupational therapy	Independent Living Skills Survey, Social Activities Scale, The Profile of Adaption to Life, GAS, Expanded BPRS, Brief Symptom Inventory, Rosenberg Self-Esteem Scale, Letiman Quality of Life Scale
Tsang and Pearson (2001)	97	RCT	Willingness to participate,18-50 years, unemployed, previous occupation: blue collar, low-level clerical or service industry, education level: no less than 5 years of primary school & no more than 5 years secondary school, no less than 1 cumulative year of hospitalisation, diagnosis of schizophrenia made by medical practitioner. Community, China	E1: Work-related social skills training with follow up support (3 months) E2: Work-related social skills training no follow up C: Standard outpatient care	Two part measure of work related social competence, Motivation checklist, Follow-up questionnaire – employment status
Individualised client-centred, occupational therapy interventions					
Cook et al (2009)	44	RCT	>16 years, diagnosis of psychosis, eligibility for enhanced care programme, score 2 or more on the Health of the Nation Outcome Scale (HoNOS) for problems with ADL, disability or occupation and activities. Community, U K	E: Occupational therapy and Treatment as Usual (TAU) C: TAU	Social functioning scale, Scale for the Assessment of Negative Symptoms, Engagement in employment related activity in last three months
Table 2.8 The characteristics of all the included studies (continued)					

Edgelow and Krupa (2011)	24	RCT	People with Severe Mental Illness (SMI) living in the community. Community, Canada	E: Occupational therapy: Action Over Inertia (AOI) & Assertive Community Treatment (ACT), C: ACT	24 hour time diaries, Profile of Occupational Engagement for People with Schizophrenia (POES)
Katz and Keren (2011)	18	CTT	Schizophrenia or schizoaffective disorder, deficits in one of the executive function measures, 20-55yrs. Acute Hospital, Israel	E: Occupational therapy: Occupational Goals Intervention (OGI) C: Frontal Executive Program	Wisconsin Card Sorting Test, Weschler Adult Intelligence Scale, Behavioural Assessment of Dysexecutive Syndrome, Executive Function Performance Test (EFPT), Routine Task Inventory-Expanded, Activity Card Sort, Reintegration Normal Living Index
Lindstrom et al (2012)	17	OD	Severe consequences in everyday life resulting from schizophrenia/ psychotic disorder, high level of assistance by community care workers, motivation to participate in rehabilitation focussed on daily occupations. Sheltered and supportive housing facilities and real-life situations, Sweden	Occupational therapy: Everyday Life Rehabilitation (ELR)	Goal Attainment Scaled (GAS), Assessment of Motor & Process Skills, Assessment of Social Interaction, Satisfaction with Daily Occupations, ADL-taxonomy with an effort-scale, Symptom Check List-90

Table 2.8 The characteristics of all the included studies (continued)

Mairs and Bradshaw (2004)	17	OD	18-65 year, diagnosis schizophrenia or schizophrenia (ICD-10), life skill deficit(s) identified on Canadian Occupational Performance measure (COPM) and/ or by the care co-ordinator/ multi-disciplinary team (MDT), client wanted to participate and capable of giving informed consent, Responsible Medical Officer consented to inclusion. Setting; participant's place residence, United Kingdom	Life skills training programme	PANNS, SFS
Activity focussed, occupational therapy group interventions					
Buchain et al (2003)	26	RCT	Psychotic symptoms >5 years, 3 anti-psychotics of 2 chemical classes, Brief Psychiatric Rating Scale (BPRS) at least 45 points, decreasing BPRS at least 20% compared to initial observation, after a treatment with up to 20 mg/day of haloperidol, for 6 weeks. Hospital, Brazil	E: Occupational therapy and psychopharmacological treatment C: Psychopharmacological treatment only	Scale for Interactive Observation in Occupational Therapy (EOITO)

Table 2.8 The characteristics of all the included studies (continued)

Hayes et al (1991)	8	CCT	Schizophrenia – DSM-III-R, at least 2 hospital admissions for schizophrenia, judged to have deficit in social interaction. Day centre of an acute psychiatric Hospital, Australia	E1: Activity therapy (AT) E2: Social skills training (SST)	Level of social engagement, Global Assessment Scale (GAS), Brief Psychiatric Rating Scale, (BPRS), Schedule for the assessment of negative Symptoms (SANS), Simulated Social Interaction Test (SSIT), Simple Rathus Assertiveness Schedule (abandoned)
Hoshi et al (2013)	59	CCT	Diagnosed with schizophrenia (ICD-10), hospitalised >1 year. Psychiatric hospital, Japan	E: Subject-chosen activity group C: Therapist-chosen activity group	Positive and Negative Syndrome Scale (PANSS) (Japanese version), GAF (Global Assessment of Functioning) (Japanese version)
Tanaka et al (2014)	46	CCT	Acute diagnosis diagnosed as schizophrenia or schizoaffective disorder ICD-10. Acute inpatient unit, Japan	E: Early occupational therapy for patients with schizophrenia (E-OTAS) + conventional occupational therapy (C-OT) C: C-OT only	Functional Independence Measure, BPRS

Table 2.8 The characteristics of all the included studies (continued)

Cognitive occupational therapy interventions					
Hadas-Lidor et al (2001)	72	RCT	Schizophrenia (DSM-IV), different stages of rehabilitation, stable medication. Community day rehabilitation centre, Israel	E: Instrumental Enrichment (IE) C: Traditional occupational therapy	IADL questionnaire, Work and Residence Status Scales, Fitts Self-Concept Scale, Two elements of Learning Potential Assessment Device, Rawen Progressive Matrices, 4/9 of tests General Aptitude Test Battery
Odes et al (2011)	71	OD	Patients with schizophrenia admitted consecutively to a closed psychiatric ward 1999-2000. In-patient closed psychiatric ward, Israel	Occupational therapy	MEDYN (comprehensive functional assessment scale), BPRS, Readmission
Raweh and Katz (1999)	19	CCT	Diagnosis schizophrenia (DSM-IV), outpatients, stabilized on medication, living in community with families or care givers. Occupational Therapy Department or Activity Centre, Israel	E: Occupational Therapy C: Work Activities	BPRS, Allen Cognitive Level (ACL-90), Routine Task Inventory (RTI-2), Awareness questionnaire
Table 2.8 The characteristics of all the included studies (continued)					

Sample sizes and settings

The sample sizes of the included studies ranged from eight to 97 participants. The settings of the studies were characterised by the participant's place of residence at the point of the study; eight studies were carried out in acute hospitals and 10 studies were carried out in the community, which included sheltered accommodation and day rehabilitation services. The studies were carried out in nine different countries, with the highest frequency set in the USA and Israel (four in each). Two studies were carried out in the UK by Cook et al (2009) and Mairs and Bradshaw (2004).

Occupational need

Occupational need or the need for occupational therapy was stipulated in the inclusion criteria of four out of the 18 studies and these were all in the category of individualised client-centred occupational therapy interventions. Occupational therapy interventions were both the experimental and control interventions in ten out of the fourteen RCT and CCT studies.

Outcome measures

Approximately half of the outcome measures were relevant to the outcomes of the review, with the majority measuring occupational performance in some format. Out of these, 26 of the outcome measures were used in only one study each; the Global Assessment Scale (GAS) (Hayes et al 1991, Liberman et al 1998) and the Social Functioning Scale (SFS) (Cook et al 2009, Mairs and Bradshaw 2004) were each used twice.

2.4.4 Occupational therapy intervention descriptions

The description of occupational therapy within the studies was wide-ranging with no two studies reporting interventions in the same manner. Table 2.9 summarises the descriptions of the occupational therapy interventions reviewed using *TIDieR checklist* (Hoffmann et al 2014).

Occupational therapy interventions using the *Template for Intervention Description and Replication (TIDieR) checklist* (Hoffmann et al 2014)			
Lead author (reference)	**Description of intervention: Theory; goal of intervention; materials and procedures**	**Who provided (Pro)?** **Mode of delivery (MoD) & tailoring (T)**	**Sessions: Total number (No);** **Intensity (I)** **Frequency (Fr) & Duration (Dur)** **Measurement of Fidelity (Fid) & Adherence (Adh)**
Life skills training, as an occupational therapy intervention			
Brown et al (2002)	**Grocery shopping intervention (experimental)** **Theory** Learning theory **Goal** Establishment of grocery shopping skills. **Procedures** Multiple learning strategies including: Repeated practice with feedback; motivational incentives; situated cognitive approaches; cuing. **Materials** Scripting of the process.	**Pro** not stated **MoD** not stated **T** not stated	**No** nine sessions **I** not stated, **Fr & Dur** not stated, **Fid** not stated, **Adh** measured by number sessions attended
Chan et al (2007)	**Transforming Relapse and Instilling Prosperity (TRIP) (experimental)** **Theory** Insight and health improved by learning adaptive life skills and knowledge of illness. **Goal:** Better insight, health and reduced relapse rates. **Procedures:** Semi-structured format, didactic presentations and open discussions, focus 'illness orientation' and 'health orientation'. **Materials** Sessions outlined10 topics of Illness management.	**Pro** occupational therapist **MoD** group **T** not stated	**No** 10 **I** 50 mins **Fr** (10 sessions over two weeks) **Dur** two weeks **Fid & Adh** not stated
Table 2.9 Descriptions of occupational therapy interventions			

Chan et al (2007) (continued)	**Ward Occupational Therapy (WOT) (control)** **Theory** Activities health approach. **Goal** Maintain activities health during hospitalisation**.** **Procedures** Normal routine selected by the patient from a typical array of work, rest and leisure activities. **Materials** Variety of clerical, craft, work tasks, and recreational activities.	**Pro** occupational therapist **MoD** group **T** not stated	**No** 10 **I** 50 mins **Fr** (10 sessions over two weeks) **Dur** two weeks **Fid & Adh** not stated
Duncombe et al (2004)	**Teaching cooking skills** (experimental: home & control: clinic) **Theory** Use of usual context supports the skill learning. **Goal** Functional living skills: cooking. **Procedures** Sessions 1-3 = cooking lessons; session 2-3 near transfer of task; copy of guidelines given and discussed. **Materials** Guidelines for cooking.	**Pro** research associates **MoD** 1:1 **T –** not stated	**No** 4, **I** not stated **Fr** weekly **Dur** 4 weeks **Fid** measurement not stated (trained in protocol) **Adh** not stated
Grimm et al (2009)	**Teaching meal preparation skills - experimental** **Theory** Acquisitional frame of reference and psycho-educational approach. **Goal** Acquisition of meal preparation skills. **Procedures** Therapists use protocols as a guide whilst exercising clinical judgement, each session included: area of meal preparation; psychoeducational component (i.e. a script, activities and methods) and breaking recipe down into four tasks. **Materials** Protocols and recipes for 10 sessions.	**Pro** occupational therapists **MoD** group **T** not stated	**No**10 **I** up to 2 hours, **Fre** 10 sessions over 12 weeks **Dur** over 12 weeks, **Fid** not stated **Adh** minimum number of sessions attended was recorded

Table 2.9 Descriptions of occupational therapy interventions (continued)

Grimm et al (2009)	**Cooking group - control** **Theory** Acquisitional frame of reference. **Goal** Acquisition of meal preparation skills. **Procedures** Therapists asked to provide 'treatment as usual'. **Materials** Recipes for 10 sessions.	**As above**	**As above**
Liberman et al (1998)	**Skills training: U.C.L.A. Social and Independent Living Skills Program (experimental) and monthly appointments with psychiatrist, followed by 18 months case management.** **Theory** Social learning theory and operant conditioning. **Goal** Independent living skills. **Procedures** Occupational therapist and three para-professionals took turns to lead four skills training modules (basic conversation, recreation for leisure, medication management, and symptom management). **Materials** Trainers manual, participants workbook and demonstration video.	**Pro** occupational therapist and three para-professionals **MoD** not stated **T** not stated	**No** not stated **I** 3 hours **Fr** 4 days week **Dur** 6 months **Fid** fidelity to manuals rated weekly by supervisor **Adh** not stated
	Psycho-social occupational therapy (control) and monthly appointments with psychiatrist, followed by 18 months case management. **Theory** not stated **Goal** Supportive therapy **Procedures** Expressive, artistic and recreational activities; encouraged to individualise interests and abilities through activities, discussing feelings and personal goals. **Materials** Activities.	**Pro** three occupational therapists **MoD** 1:1 and group **T** not stated	**No** not stated **I** 3 hours **Fr** 4 days week **Dur** 6 months **Fid** not stated **Adh** not stated

Table 2.9 Descriptions of occupational therapy interventions (continued)

Tsang and Pearson (2001)	**Work-related social skills training (SST)** **Theory** Hierarchical stages of learning based on the foundation of basic social skills and basic survival social skills, followed by core work-related skills. **Goal** Finding and keeping a job. **Procedure** 10 sessions related to finding and keeping a job. Program focussed on generalising skills from one situation to another. **Materials** Training package, structured sessions, warm-up activities, instruction, demonstration, role play, feedback and homework assignments. **Experimental 1. SST plus follow up support** monthly meeting by occupational therapist; participants shared experiences, developed positive strategies and gave moral support. **Experimental 2. SST only**	**Pro (SST)** occupational therapist and welfare worker **Follow up** occupational therapist **MoD** group **T** not stated	**SST** **No** 10**, I** 1.5-2hours**,** **Fre** weekly**, Dur** 10 weeks**, Fid** not stated, **Adh** participants contacted by phone if meeting was missed. **Follow up support** **No** 3**, I** not stated**, Fre** monthly**, Dur** three months**, Fid** not stated**, Adh** as above
Individualised client-centred, occupational therapy interventions			
Cook et al (2009)	**Individualised occupational therapy (experimental)** **Theory** Occupational science and client-centred approach **Goal** Improved social functioning, reduced negative symptoms and improved employment outcomes. **Procedures** Individualised client centred approach, using occupational therapy process and intervention schedule. **Materials** Occupational therapy intervention schedule.	**Pro** senior occupational therapists **MoD** 1:1 **T** yes**:** select and adapt activities to meet individual's goals (not the forms of therapy).	**No & I** not stated **Fr** not stated **Dur** up to 12 months **Fid** monitored via clinical supervision **Adh** audited via participants therapy notes

Table 2.9 Descriptions of occupational therapy interventions (continued)

Edgelow and Krupa (2011)	**Action Over Inertia (AOI) – experimental** **Theory** Canadian Model of Occupational Performance and Engagement (CMOP-E) (Townsend and Polatajko, 2007) and Recovery. AOI occupation-based intervention to improve occupational balance and engagement with people with severe mental illness (SMI). **Goal** Reconnect clients with meaningful activity, promoting health and well-being. **Procedures** Use of workbook in an individualized manner (five phases), promotes full collaboration to improve occupational balance and engagement. **Materials** Intervention presented in workbook.	**Pro** occupational therapists **MoD** 1:1 **T** manual is guide and interventions individualised to each person.	**No** 12**, I** not stated**,** **Fre** once a week **Dur** twelve weeks **Fid** measurement not stated (trained in how to deliver the treatment) **Adh** not stated
Katz and Keren (2011)	**Occupational Goals Intervention (OGI) (experimental)** **Theory** Goal Management Training (GMT) applied to daily tasks. **Goal** Executive functioning and activity and participation. **Procedures** Goal Management Training with focus on individual choice of meaningful activities, strategy learning using activities and everyday tasks, and a debriefing of activity performance at the end. **Materials** Five stages to OGI program outlined.	**Pro** occupational therapists **MoD** 1:1 **T** focus on individual choice of meaningful activities	**No** 18, **I** 1-1.5 hours, **Fr** weekly, **Dur** 6-8 weeks, **Fid** measurement not stated (therapists trained in treatment) **Adh** not stated
	Activity training approach (control) **Theory** Activity-specific routines can be taught. **Goal** Activity performance to become habitual. **Procedures** Participant is trained to carry out specific tasks that he/she needs to or wants to do and practice their performance so they are habitual. **Materials** not stated.	**Pro** occupational therapists **MoD** 1:1 **T** trained in tasks that he/she wants to do	As above

Table 2.9 Descriptions of occupational therapy interventions (continued)

Lindstrom et al (2012)	**Everyday Life Rehabilitation (ELR)** **Theory** ELR is a model for integrated rehabilitation, based on Occupational Therapy Intervention Process Model (OTIPM, Fisher 2009). **Goal** To enable meaningful daily occupations for people with psychiatric disabilities living in supported or sheltered housing. **Procedures** Use OTIPM to facilitate close collaboration, recovery focus, client centeredness, goal-setting based on user choices, graded activities, occupation-based training in real-life settings, individually set time-frames, and support during a maintenance phase after goal attainment. Occupational therapist and community care worker met between sessions to collaborate and plan activities to integrate and maintain progress into daily activities **Materials** ELR model and OTIPM.	**Pro** occupational therapists **MoD** 1:1 **T** goals tailored to individual needs and timescales.	**No** not stated **I** 1-2 hours **Fre** once or twice a week **Dur** 2-17 months not stated **Fid & adh** not stated
Mairs and Bradshaw (2004)	**Life skills training programme (experimental)** **Theory** Model of functional deficits **Goal** Life skills **Procedures** First three sessions – assessment and engagement, individualised formulation guided therapist in devising an appropriate intervention. Sessions 4-12 – life skills training intervention, including psychoeducation, activity scheduling, modelling, shaping and reinforcement. **Materials** Manual of case formulation approach to life skills training.	**Pro** occupational therapists **MoD** 1:1 **T** individual formulations of functional deficits; session intensity responsive to individual needs.	**No** 12 sessions, **I** varied in duration (see tailoring) **Fre** 12 sessions over **Dur** 4 months **Fid** occupational therapists (training in therapy) fortnightly supervision discussed cases**, Adh** not stated

Table 2.9 Descriptions of occupational therapy interventions (continued)

Activity focussed, occupational therapy group interventions			
Buchain et al (2003)	**Occupational therapy (experimental)** **Theory** Therapist-patient-activity creates an environment for learning and structured development. **Goal** Social (re) insertion using the daily routine as an organizing axis. **Procedures** Free choice of activities, dynamics of the group were; group of activities and group activity. **Materials** Activities	**Pro** occupational therapist **MoD** group **T** not stated	**No & I** not stated **Fr & Dur** not stated **Fid & Adh** not stated
Hayes et al (1991)	**Activity therapy (AT) (experimental)** **Theory** Activity groups facilitate social interaction, producing tangible product. **Goal** Improved social skills in naturalistic settings. **Procedures** Construction activity; reduced to its smallest parts and presented one step at a time. **Materials** Construction materials.	**Pro** therapist (background not stated) **MoD** group **T** not stated	**No** not stated **I** 45 minutes **Fr** twice weekly **Fid & Adh** not stated
Hoshi et al (2013)	**Subject-chosen activity group (experimental)** **Theory** Client-centred occupational therapy practice. **Goal** Reduced psychiatric symptoms and improved psycho-social functions. **Procedures** Canadian occupational performance measure (COPM) used to understand choices. Participants performed chosen activities. **Materials** COPM	**Pro** occupational therapists **MoD** group **T** to participants activity choices	**No** not stated **I** up to 2 hours **Fr** up to once a week **Dur** up to 6 months **Fid & Adh** not stated

Table 2.9 Descriptions of occupational therapy interventions (continued)

Hoshi et al (2013)	**Therapist chosen activity group (control)** **Theory** not stated **Goal** Reduced psychiatric symptoms and improved psycho-social functions. **Procedures** Participant interview conducted without COPM and therapist chose activities based on treatment recommendations. **Materials** not stated	**Pro** Occupational therapist **MoD** group **T** not stated	As above
Tanaka et al (2014)	**Early occupational therapy for patients with schizophrenia (E-OTAS) (one month) + (conventional occupational therapy C-OT outlined below) = experimental** **Theory** Occupational therapy provides the opportunity to improve task performance; cognitive disorganisation; rebuild and sustain partnerships. **Goal** Functional independence. **Procedures** Simple structured activities and exercises (mostly non-verbal). **Materials** Not stated	**Pro** occupational therapists **MoD** 1:1 **T** structured activities to patient preferences + C-OT (below)	**No** not stated **I** 10-30 minutes **Fre 2-**3 times a week **Dur** 1 month from start admission **Fid** & **Adh** not stated + C-OT (below)
	No occupational therapy (one month) + Conventional occupational therapy (C-OT) (Control only) **Theory** and **Goal** as described for E-OTAS. **Procedures** Standard occupational therapy activities. **Materials** Not stated	**Pro** occupational therapists **MoD** group **T** not stated	**No** not stated**, I** 30-120 minutes**, Fre** 2-5 times a week**, Dur** not stated (starts one month after admission)**, Fid & Adh** not stated

Table 2.9 Descriptions of occupational therapy interventions (continued)

Cognitive occupational therapy interventions			
Hadas-Lidor et al (2001)	**Instrumental Enrichment (IE) (experimental)** **Theory** Dynamic cognitive intervention through Mediated Learning Experience (MLE). **Goal** Improve cognitive ability and independence (ADL and occupational). **Procedures** Each session includes: Cognitive exercises; analysis of performance and application of learning in client's ADL situation. **Materials** Paper and pencil exercises.	**Pro** occupational therapist **MoD** 1:1 & group **T** adapted to abilities & needs.	**No** not stated, **I** 1 hour (groups - not stated), **Fr** 2-3 weekly (groups every few weeks), **Dur** 1 year, **Fid** measurement not stated (trained in how to deliver the treatment) **Adh** not stated
	Traditional occupational therapy (control) **Theory** not stated **Goal** not stated **Procedures** Functional tasks and expressive activities. **Materials** not stated	**Pro** occupational therapist **MoD** 1:1 & group **T** not stated	As above
Odes et al (2011)	**Occupational therapy (experimental)** **Theory** Allen Cognitive Levels (ACL) model. **Goal** Social, cognitive and task oriented functioning. **Procedures** Social, cognitive and functional skills training, using cognitive-behavioural format. **Materials** not stated	**Pro** not stated **MoD** group (homework given in individual & group settings) **T** not stated	**No** not stated **I** 3-4hours **Fre** 5 days a week **Dur** not stated **Fid & Adh** not stated

Table 2.9 Descriptions of occupational therapy interventions (continued)

Raweh and Katz (1999)	**Occupational therapy (experimental)** **Theory** Cognitive disabilities model. **Goal** Improve performance on routine tasks. **Procedures** Low level and high level tasks provided as choices – patients able to choose what interested in and with consideration of cognitive function. **Materials** Tasks	**Pro** occupational therapist **MoD** not stated **T** tasks matched to interests and cognitive ability	**No** 8, **I** 1 hour **Fre** 3 times a week **Dur** 2 – 6 months approximately **Fid** & **Adh** not stated
	Work Activities, Community Activity Centre (control) **Theory** Maintaining clients function through productive work. **Goal** Maintaining functioning. **Procedures** Work in industrial type tasks, not specifically matched to cognitive functional levels. **Materials** Work type tasks.	**Pro** occupational therapists **MoD** not stated **T** not stated	As above

Table 2.9 Descriptions of occupational therapy interventions (continued)

Occupational therapy delivery

The mode of delivery of seven of the experimental interventions was via a group, seven on a one-to-one basis, with two studies delivering the intervention with a combination of group and individual work and two not stating the mode of delivery. Twelve of the experimental interventions were provided by occupational therapists, with two being provided by occupational therapists and welfare or paraprofessionals. In two of the studies it was unclear as to the professional orientation of the provider and in another two studies it was unclear/ not stated who provided the intervention. Half of the experimental interventions were tailored to individual participant needs. Six studies reported fully on the sessions (total number, intensity, frequency and duration) (Chan et al 2007, Grimm et al 2009, Tsang and Pearson 2001, Katz and Keren 2011, Mairs and Bradshaw 2004, Raweh and Katz 1999). The frequency of sessions was reported the most frequently (15 out of 18 studies) and the total number of sessions was reported the least (nine out of 18 studies).

Fidelity and adherence

‘Treatment fidelity has been considered to be treatment integrity-that is, whether the treatment was delivered as intended’ (Bellg et al 2004, p.444).

Measurement of fidelity to the interventions was stated in approximately three (17 percent) of the studies. In contrast, adherence to treatment refers to the extent to which a participant’s behaviours comply with medical or health advice (Persch and Page 2013). Actual measurement of adherence to treatment was reported only slightly better four (22 percent) of the studies.

2.4.4.1 Lifeskills training, as an occupational therapy intervention; descriptions

The predominant theory underpinning life skills training, as an occupational therapy intervention, was derived from various learning theories (see Table 2.9). The experimental interventions reported the use of scripting, session outlines, guidelines, protocols or a manual to guide the intervention. Where occupational therapy was also the control intervention there was less stipulation of the processes to follow. Both Chan et al (2007) and Liberman et al (1998) compared different types of occupational therapy interventions; the experimental and control interventions had different goals.

2.4.4.2 Individualised client-centred occupational therapy interventions; descriptions

The individualised client-centred occupational therapy interventions were all, based on occupational therapy theory and models and each study stated these differently. All the experimental interventions were tailored to individual needs from a structured format, which was including:

- Occupational therapy intervention schedule (Cook et al 2009)
- Action Over Inertia (AOI) workbook (Edgelow and Krupa 2011)
- Occupational Goals Intervention (OGI), programme outlined, (Katz and Keren 2011)
- Occupational Therapy Intervention Process Model OTIPM (Lindstrom 2012)
- Manual of case formulation approach to life skills training, (Mairs and Bradshaw 2004)

Three studies delivered training in the intervention for those providing it; however fidelity to the treatment interventions was measured by only two studies (Cook et al 2009, Mairs and Bradshaw 2004). Adherence to treatment was measured in one study (Cook et al 2009).

2.4.4.3 Activity-based, occupational therapy group interventions; descriptions

All four activity-based, occupational therapy group interventions stated occupational therapy theory as the foundation for the intervention and this was described differently in each study. The mode of delivery was via the use of groups; in addition to this Tanaka et al (2014) also used one-to-one activities in the experimental arm for one month, before the group-work approach began. The materials used tended to be activities or tasks. Fidelity and adherence to the intervention were not reported in any of the studies.

2.4.4.4 Cognitive occupational therapy intervention; descriptions

There were three different theories underpinning cognitive occupational therapy interventions:

- Dynamic cognitive intervention through Mediated Learning Experience (Hadas-Lidor et al (2001)
- Allen Cognitive Levels (ACL) Model (Odes et al 2011)
- Cognitive disabilities model (Raweh and Katz (1999)

The intervention specifications for occupational therapy when used as a control were less explicitly described and the goals differed from the experimental intervention, for example in the study carried out by Raweh and Katz (1999), the

experimental intervention goal was to improve performance on routine tasks and the goal of the control was to maintain functioning.

2.4.5 Outcome of interventions

The reported effects of the interventions on the primary and secondary outcomes are reported in Table 2.10. The best evidence synthesis for each of the intervention categories follows; this was conducted using the outcomes in Table 2.10 and the Best evidence synthesis guidelines in Illustration 2.1.

SMD = standardised mean difference; CI = 95% confidence interval; E = experimental group; C = control group; RCT = randomised controlled trial; nr = not reported; ns = no significant differences between groups.						
First author (reference)	Design	Methodological quality	Participation in activities of everyday life			Quality of life and health-related quality of life
			Participation and satisfaction with activities of everyday life	Occupational performance in activities of daily living/ functional ability	Time use in activities	
			Mean (sd) SMD Baseline (95% CI)	Mean (sd) SMD Baseline (95% CI)	Mean (sd) SMD Baseline (95% CI)	Mean (sd) SMD Baseline (95% CI)
Life skills occupational therapy interventions						
Duncombe et al (2004)	RCT	Low	not measured	ns	not measured	not measured
Liberman et al (1998)	RCT	Low	not measured	**GAS** ns **Indep living skills** E=2.70 (1.50); C=7.22(1.46) (F=4.68, df=1,207, p=0.03) **Social Activities Scale** ns	not measured	**Lehman QoL** ns

Table 2.10 Effects of occupational therapy on participation in activities of everyday life, quality of life & health related quality of life

Grimm et al (2009)	RCT	High	not measured	ns	not measured	not measured
Tsang and Pearson (2001)	RCT	Low	not measured	**Work related-social competencies** E^1 38.00; E^2 39.00; C 18.77 (F=14.79, df=2,87, p<0.01) **Follow-up assessment of employment** E (n=20) v C (n=1) (χ^2 =20.02, df=2, p<0.01)	not measured	not measured
Client-centred occupational therapy interventions						
Cook et al (2009)	RCT	High	ns & nr	ns	not measured	not measured
Edgelow and Krupa (2011)	RCT	Low	ns	not measured	ns & nr	not measured
Activity focussed occupational therapy group interventions						
Buchain et al (2003)	RCT	Low	not measured	**EOITO** E v C (F=5.129, p=0.033)	not measured	not measured

Table 2.10 Effects of occupational therapy on participation in activities of everyday life, quality of life & health related quality of life (continued)

Chan et el (2007)	RCT	Low	not measured	not measured	not measured	**SF-36** **Physical** ns **Role-physical** (F=5.27,p=0.024) **Bodily pain** ns **General health** (F=5.56,p=0.021) **Vitality** (F=9.29,p=0.003) **Social Functioning** (F=14.5,p=0.000) **Mental health** (F=10.1,p=0.002) **Physical health component** (F=8.75,p=0.004) **Mental health component** (F=19.4,p=0.000)
Cognitive occupational therapy interventions						
Hadas-Lidor et al (2001)	RCT	Low	not measured	ns	not measured	not measured

Table 2.10 Effects of occupational therapy on participation in activities of everyday life, quality of life & health related quality of life (continued)

2.4.5.1 Life skills training, as an occupational therapy intervention

The best evidence synthesis for life skills training, as an occupational therapy intervention drew from one high quality RCT (Grimm et al 2009) and three low quality RCTs. Liberman et al (1998) found that patients who received skills training showed significantly greater independent living skills. Tsang and Pearson (2001) found that participants who received a vocational social skills training program and follow up were statistically more successful at finding and keeping a job than participants in either of the other two groups. In contrast the other half of the studies found no statistically significant difference (see Table 2.10). None of the studies specifically measured participation and satisfaction in activities of everyday life or time use in activities. Thus on the basis of conflicting results and only partial reporting on the primary outcome, there is no evidence for the effectiveness of life skills training, as an occupational therapy intervention on participation in activities of everyday life. Only Liberman et al (1998) measured Quality of Life (QoL) and found no significant difference between the two groups. Therefore as a low quality RCT there is only indicative evidence for the effectiveness of life skills, occupational therapy interventions on quality of life/ health-related quality of life.

2.4.5.2 Individualised, client-centred occupational therapy interventions

The best evidence synthesis found that the primary outcome of participation in activities of everyday life was partially reported by both of the RCTs: one had high methodological quality (Cook et al 2009) and one low quality (Edgelow and Krupa 2011). Both studies measured participation and satisfaction with activities of everyday life; Cook et al (2009) measured these via engagement in employment related activity and Edgelow and Krupa (2011) via the Profile of

Occupational Engagement for People with Schizophrenia (POES), neither study reported statistically significant findings. Cook et al (2009) partly measured functioning using the Social Functioning Scale (SFS) and differences were not statistically significant. Edgelow and Krupa (2011) also measured time use and results were not statistically significant. Thus there was no evidence for the effectiveness of individualised client-centred occupational therapy interventions on participation in activities of everyday life. There was no evidence regarding quality of life or health-related quality of life as neither study measured it.

2.4.5.3 Activity-based, occupational therapy group interventions

The best evidence synthesis was based on two RCTs; both studies were assessed as being of low methodological quality. Only Buchain et al (2003) partially measured participation in activities of everyday life (occupational performance in activities of daily living/ functional ability) and found statistically significant results. No other aspects of the primary outcome were measured by either study. Therefore there is only indicative evidence for the effectiveness of activity-based, occupational therapy group interventions on participation in activities of everyday life. Quality of life was only measured by Chan et al (2007) who found that participants in the TRIP programme had significantly better insight and health than the comparison group. Therefore there is indicative evidence for the effectiveness of activity-based, occupational therapy group interventions on quality of life/ health-related quality of life.

2.4.5.4 Cognitive occupational therapy interventions

The best evidence synthesis identified one RCT study, which was of low methodological quality, which partially measured participation in activities of everyday life via occupational performance in activities of daily living/functional

ability and no statistically significant results were found. Quality of life was not measured. Thus there was no evidence for the effectiveness of cognitive occupational therapy interventions on participation in activities of everyday life or quality of life in this study.

2.5 Discussion

2.5.1 Summary of the evidence

This systematic review focussed on the effectiveness of occupational therapy in enabling people with a diagnosis of psychosis to improve their participation in activities of everyday life; four different intervention categories were identified (see Section 2.4.3):

- It was established that there was indicative evidence for the effectiveness of activity-based, occupational therapy group interventions on participation in activities of everyday life and quality of life/ health-related quality of life.
- No evidence was found for the effectiveness of life skills training, as an occupational therapy intervention on participation in activities of everyday life; however there was indicative evidence for its effectiveness on quality of life/ health-related quality of life.
- There was no evidence for the effectiveness of individualised client-centred or cognitive occupational therapy interventions on participation in activities of everyday life or quality of life/ health-related quality of life.

The results must be considered in the context of the small numbers and generally low methodological quality of the studies that the results were taken from (discussed further in section 2.5.2) and also due to sparse reporting on key outcomes of the systematic review (discussed further in section 2.5.3). It is also

important to note that lack of evidence is not evidence of no effect (Bullock and Bannigan 2011). More high quality effectiveness studies that measure the outcomes of the systematic review need to be conducted before firm conclusions on effectiveness can be drawn.

2.5.2 Methodological quality

Overall the methodological quality of studies in this review were limited, with only two of the nine RCTs being assessed as having high quality; furthermore all the CCTs and ODs were assessed as low quality. Key issues were in regards to the reporting of the internal validity. Internal validity is achieved:

> 'If the experimenter can validly infer that the results obtained were owing to the influence of the experimental variable (i.e. the experimental variable affected the dependent variable), then the experiment has internal validity' (Bowling 2009 p.241).

The descriptive criteria, of the interventions were sparsely reported; without this information it is not possible for the intervention to be replicated in future research studies. These two key areas (internal validity and the description of the intervention) are fundamental components to achieving methodological quality, influencing the strength of the validity and reliability of the results.

2.5.3 Measurement and reporting on outcomes of the systematic review

The primary and secondary outcomes of the systematic review were only partially measured and reported on in all the studies, therefore there are gaps in the evidence from which the conclusions about effectiveness were drawn. The outcomes not measured may or may not have been affected by the intervention; this is unknown without measurement.

It raises the question: How appropriate are the constructs are being identified and measured in this area of occupational therapy research? Given the primary

outcomes for occupational therapy used in this review were derived from WFOT (2012) it is of concern that studies do not measure the outcome of interest. Some studies were excluded from the review because none of these outcomes were identified (see Table 2.5). Having consensus on the expected outcomes of occupational therapy is critical, in order to know what to measure. The need to have international consensus on a core set of outcome measures in occupational therapy research has been highlighted (Steultjens 2002), and is supported by this review, with 14 different outcome measure tools being used across the nine studies. With such a wide-range of outcome measures it was at times a challenge to make decisions on the validity of the outcome measures to measure the outcomes of the systematic review. For example, Cook et al (2009) measured 'engagement in employment related activity,' this was within the realms of participation and satisfaction with activities of everyday life. Whereas the follow-up questionnaire utilised by Tsang and Pearson (2001) measured employment status and was excluded because it measured work status and not occupational performance, functioning or participation.

2.5.4 Best evidence synthesis

The outcomes of best evidence synthesis were drawn from two high quality RCTs and seven low quality RCTs; nine low quality CCTs and ODs were excluded, as a sensitivity analysis. This has been recognised as a strict process of synthesis (Steultjens et al 2004); however this rigour also increases the validity of the findings of the review. The best evidence synthesis (see Section 2.3.8.1) was chosen to quantify the current research evidence on effectiveness, knowing that meta-analysis was most likely not possible due to the heterogeneity of the studies. Whilst this turned out to be the case, there were a

disappointing number of high quality studies that robustly measured and reported on the outcomes set out in this review. The best-evidence synthesis has given a summary of the current evidence and importantly identified the areas for development in future effectiveness research in this area; what needs to researched and also in what manner.

2.5.5 Systematic review criteria

The criteria used for the systematic review excluded 29 of the full research papers accessed (see Table 2.6); two studies were excluded because occupational therapy was not specified as per the review specification (Ojeda et al 2012, Sachs et al 2012). This may have been because of the specific occupational therapy description used. In contrast to this review, Arbeston and Logsdon (2011) and Gibson et al (2011) used a broader description, including studies within occupational therapy's scope of practice. Studies of multi-disciplinary team (MDT) interventions, some of which included occupational therapy and showed promising results, for example, Cook and Howe (2003), were excluded from the review because the efficacy of occupational therapy could not be stated. This means that actual evidence of the effectiveness of occupational therapy may be being missed from the occupational therapy research evidence base.

2.5.6 Inclusion/ exclusion criteria within individual studies

Occupational need or the need for occupational therapy was stipulated in the inclusion criteria for less than a quarter of the 18 studies identified as appropriate for the review. This is a fascinating and critical phenomenon because, without a qualifier of a particular need/ problem existing, how possible is it to know that occupational therapy would be appropriate intervention to use

and have some effect? If a need or problem does not exist or is not specified, it can be reasonably surmised that it will not be affected by an intervention to treat it.

2.5.7 Occupational therapy as the control and experimental intervention

Half of the studies (nine) had occupational therapy as both the experimental and control arms of the study. This created some issues when deriving information about the effectiveness of occupational therapy. For example Grimm et al (2009) found no significant difference between the two groups in terms of independence or level of assistance at posttest. However when both groups were combined there was a significant improvement from pretest to posttest. Perhaps consideration of a non-occupational therapy control would enable the effectiveness of occupational therapy to be more clearly analysed?

2.5.8 Different goals of the experimental and control interventions

A number of studies were aiming to achieve different goals from the control and experimental interventions (Chan et al 2007, Liberman et al 1998, Katz and Keren 2011, Hadas-Lidor et al 2001,Raweh and Katz 1999). For example in the study by Raweh and Katz (1999), the goal of occupational therapy in the experimental intervention was to improve performance on routine tasks, whereas the goal of the control was to maintain functioning (see Table 2.9). Both of these interventions would thus indicate a different type of occupational need. It raises the question about the validity of the control and also highlights the need to differentiate between different types of occupational therapy interventions. This is important to learn from because different types of interventions are utilised to meet different needs. For example, an intervention may be found to be ineffective for a particular need, in a particular setting;

however if the findings are generalised to all occupational needs in all settings, they may not in reality reflect the level of external validity.

2.5.9 Descriptions of occupational therapy were wide-ranging

All of the studies reported occupational therapy differently, consequently it was difficult to compare interventions as 'like for like'. However the interventions were able to be grouped into four intervention categories as some similarities were seen within these groups (see Section 2.4.3). It was notable that when occupational therapy was used as the control it was often less well defined and therefore challenged the internal and external validity of the studies. The use of the *TIDieR checklist* (Hoffmann et al 2014) to list the descriptions (see Table 2.9) of the occupational therapy intervention's, highlighted the gaps in reporting about what was provided. This is an important area to address in future studies because it enables studies to be replicated and further scrutinised. Also the use of manuals, scripts, intervention schedules and outlines of group sessions (which were provided in some studies) support the replicability of research carried out. However there were a significantly low number of studies that measured fidelity to the intervention being provided and adherence to treatment from the participants in the study. Both are critical elements in ensuring the internal validity of a study.

2.6 Conclusion

In conclusion, the review found indicative evidence for the effectiveness of activity-based, occupational therapy group interventions on participation in activities of everyday life and quality of life/ health-related quality of life. No evidence for the effectiveness of life skills training, as an occupational therapy intervention on participation in activities of everyday life and indicative evidence

for its effectiveness on quality of life/ health-related quality of life. There was no evidence for the effectiveness of individualised client-centred or cognitive occupational therapy interventions on participation in activities of everyday life or quality of life/ health-related quality of life. The results must be taken in the context of the small number and generally low methodological quality of the studies that the results were taken from, and also due to sparse reporting on key outcomes of the systematic review.

The review identified and illuminated that more high quality RCTs in occupational therapy with people with a diagnosis psychosis; that measure the impact on participation in activities of everyday life are needed, in order to be able to make an informed decision on the effectiveness of occupational therapy in this area. To achieve this, these studies must include:

- Inclusion criteria inclusive of a process for identifying, participants' occupational need.
- Outcome measures that measure all the facets of participation in activities of everyday living and quality of life/ health-related quality of life, thus enabling occupational therapy theory to be tested in practice/research setting.
- Occupational therapy interventions (including control) in sufficient detail to be replicated, ideally using the *TIDieR checklist* (Hoffmann et al 2014).
- Clear methods of measuring fidelity and adherence to treatment interventions.
- High methodological quality and reporting, using the CONSORT guidance (Moher 2010).
- Comparators to occupational therapy.

Chapter 3 Methodology

3.1 Introduction

Central to the design of research studies are the philosophical assumptions and knowledge claims from which it is approached and how these are brought into the study to inform the strategy of inquiry and choice of methods (Creswell 2003). The research design is the overall structure or plan for the research, for example: descriptive or experimental and the method is the practices and techniques used to collect and analyse the data (Bowling 2009). This chapter introduces and gives an appraisal of the theoretical perspective and research design considerations that the study was approached from (see Section 3.1.1). It considers occupational therapy as a complex intervention and its relationship ship to carrying out effectiveness trials (see Section 3.1.2). It discusses how the theoretical perspective evolved as the purpose of the study was considered in more depth, in the context of the current evidence base and the *Developing and evaluating complex interventions: new guidance* (Medical Research Council (MRC) 2008). The key uncertainties in the design of an effectiveness study, of occupational therapy with individuals with a diagnosis of psychosis, living in the community are identified (see Section 3.1.3). The thesis aim is revisited in Section 3.1.4 and the study objectives are outlined. It then discusses and gives an overview of the study design (see Section 3.2) and the study method (see Section 3.3).

The study method was carried out in two phases:

- **Phase one**

  The first phase was the development of an occupational therapy intervention specification; the discussion and development of which is written up in Chapter four.

- **Phase two**

  The second phase was a feasibility study for a pragmatic randomised controlled trial (RCT); this is discussed and reported on throughout this chapter.

Meaningful service user and carer involvement was integrated into the study; this is introduced in Section 3.3.1 and discussed in the related sections throughout this chapter.

Beauchamp and Childress' (2009) moral principles are presented as an ethical framework (see Section 3.3.2) from which the ethical issues of the study were considered, again the discussions of which are integrated into the relevant sections of the feasibility study.

3.1.1 Theoretical perspectives and research design considerations

Each theoretical perspective consists of a set of assumptions or a way of looking at the world which directs attention and provides a framework for interpreting research observations (Bowling 2009). This study initially set out to explore the effectiveness of occupational therapy and was originally approached from a postpositivist perspective; a deterministic philosophy in which cause probably determines effect or outcome (Creswell 2003). The randomised controlled trial (RCT) is reported to be the most robust study design with which to investigate effectiveness of health treatments (Hotopft et al 1999).

There are two main types of RCTs that exist: ‘explanatory’ and ‘pragmatic’ (Bench et al 2013, p.38). The strength of an explanatory RCT is that it tests efficacy with strict inclusion criteria which increases internal validity; however it also reduces external validity (Bench et al 2013).

In contrast to the explanatory RCT is the pragmatic RCT which is primarily designed to answer the effectiveness question: Does the intervention work when used in normal practice? (Zwarenstein et al 2008). A tool was developed to assist trialists in making research design decisions based on a pragmatic-explanatory continuum indicator summary (PRECIS) (Thorpe et al 2009). The PRECIS recognises that the purpose of the trial determines the trial design decisions and each trial displays varying levels of pragmatism across ten design domains; it was utilized to guide these decisions in this study (see Table 3.1) (Thorpe et al 2009). The approach to developing, evaluating and being able to test the effectiveness of an occupational therapy intervention, was pragmatic, because pragmatic RCTs are primarily designed to determine the effects of an intervention under the usual conditions in which it will be provided (Thorpe el al 2009). The pragmatic theoretical perspective provided a broad framework from which to work from, as it is not committed to any one system of philosophy and reality (Creswell 2003).

3.1.2 Occupational therapy as a complex intervention

As discussed in the Introductory Chapter (see Section 1.6.4) occupational therapy has been defined as a complex intervention (Creek 2003) and meets a number of the various qualifiers as a complex intervention, as defined by the MRC (2008). Best practice requires complex interventions to be developed systematically starting with each of the key uncertainties in the design (MRC

2008, Richards 2015) (see Section 3.1.3). The main elements of the development-evaluation-implementation process of complex interventions are: developing an intervention; piloting and feasibility; evaluating the intervention; implementation and reporting at each stage (MRC 2008). The aim of this study was considered in relation to this guidance to ensure that the most appropriate research method was applied. This begins by identifying the relevant, existing evidence base, ideally through carrying out a systematic review (MRC 2008).

Pragmatic design decisions using *Pragmatic-explanatory continuum indicator summary (PRECIS),* Thorpe et al (2009)	
PRECIS domain	**Related pragmatic approach taken**
Participant eligibility criteria	Eligibility criteria specified were broad, with exclusion criteria kept to a minimum (see Section 3.4.1)
Experimental intervention flexibility	The intervention was individualised (tailored); however all objectives of the occupational therapy pathway needed to be carried out to achieve fidelity (see Section 3.4.2 & 4.5.3)
Experimental intervention practitioner expertise	Practitioner expertise was reflective of a range of practitioners, utilised directly from practice and from a range of community clinical settings (see Section 3.4.2.1)
Primary trial outcome	Chosen as a clinically meaningful outcome to participants; reflective outcomes measured in practice (see Section 3.4.4.1)
Participant compliance with “prescribed” intervention	Unobtrusive measurement of compliance; adherence to the intervention was only measured once at the end of the intervention in the study (see Section 3.6.6)

Table 3.1Summary of design decisions informed by the *PRECIS (2009)*

A systematic review was carried out (see Chapter two); it concluded that there was no evidence of effectiveness for individualised client-centred occupational therapy interventions on participation in activities of everyday life, quality of life or health-related quality of life for individuals with a diagnosis of psychosis, living in the community (see Section 2.6). The results were found in the context of a small number of studies of generally low methodological quality and sparse reporting on key outcomes of the systematic review.

In an NHS Trust, in the North of England; occupational therapy had been carried out with individuals with a diagnosis of psychosis; standardized outcome measure data had routinely indicated positive changes in their occupational performance and satisfaction with this. These interventions were not tested under research conditions or with outcomes specifically measuring participation and therefore the indication of effect required further exploration, which was carried out in this study.

3.1.3 Key uncertainties in the design of an effectiveness study of occupational therapy as a complex intervention

It was recognised that the conduct of this feasibility study needed to address some of the key uncertainties in the design of occupational therapy effectiveness studies in this area of practice, as identified in the systematic review (Chapter two). The systematic review (see Section 2.6) recommended that future effectiveness studies needed to incorporate some key elements summarised in Box 3.1. Understanding these key uncertainties would contribute to higher quality effectiveness studies and enable a more informed decision to be made regarding the effectiveness of occupational therapy in this area. As already mentioned the *CONSORT 2010 Statement* was utilised to support high quality reporting of the study (Schulz et al 2010).

A fundamental aspect for any occupational therapy effectiveness study is to identify that there is an existing occupational need before trying to recruit and treat that need: this was incorporated into the method (see Section 3.4.1.1).

- Inclusion criteria inclusive of a process for identifying participants' occupational need
- Outcome measures that measure all the facets of participation in activities of everyday living and quality of life/ health-related quality of life, thus enabling occupational therapy theory to be tested in practice/research setting
- Occupational therapy interventions in sufficient detail to be replicated, ideally using the *TIDieR checklist* (Hoffmann et al 2014)
- Clear methods of measuring fidelity and adherence to treatment interventions
- High methodological quality and reporting, using the *CONSORT 2010 Statement* (Schulz et al 2010)
- Comparators to occupational therapy

Box 3.1 Key elements supporting high methodological quality of occupational therapy effectiveness studies

3.1.3.1 Valid and reliable outcome measures of participation

How to measure participation in activities of everyday life also needed to be explored and defined, as discussed in the Introductory chapter (see Section 1.3.4).

3.1.3.2 Occupational therapy intervention description

Fundamental to any effectiveness study is the description of the intervention suitable for research. This did not exist (see Section 4.4.3.1, Step one) and therefore the first objective of the study was to develop a valid description of occupational therapy with good utility for a RCT.

3.1.3.3 Measuring fidelity and adherence

Subsequent to a valid description of occupational therapy there were two critical aspects contributing to the testing of the effectiveness of the intervention; treatment fidelity and adherence to occupational therapy.

'Treatment fidelity has been considered to be treatment integrity-that is, whether the treatment was delivered as intended' (Bellg et al 2004, p.444).

In contrast, adherence to treatment refers to the extent to which a participant's behaviours comply with medical or health advice (Persch and Page 2013). It was identified in the systematic review that the majority of effectiveness studies did not include details about how fidelity and adherence to occupational therapy were supported and measured (see Section 2.4.4). Therefore exploring how to measure both fidelity and adherence to occupational therapy formed a key part of the feasibility study.

3.1.3.4 How does occupational therapy cause change?

In addition to the elements recognised in the systematic review, it is advocated that a good understanding is needed about how the intervention causes change (MRC 2008). Therefore the study also aimed to explore more about how occupational therapy enables people with a diagnosis of psychosis to participate in activities of everyday life?

3.1.4 Study Aim and Objectives

The study aim introduced in Section 1.8 and written again in Section 3.1.4.1 was revisited in the context of the key uncertainties, in the design of a RCT of occupational therapy in this area (see Section 3.1.3). This created six objectives for the study which are outlined in Section 3.1.4.2.

3.1.4.1 Aim

To develop and evaluate an occupational therapy intervention for individuals with a diagnosis of psychosis, living in the community, to improve their participation in activities of everyday life and carry out a feasibility study for its use in a pragmatic RCT.

3.1.4.2 Objectives

To conduct a feasibility study to explore how possible it would be to carry out a pragmatic RCT, to test the effectiveness of occupational therapy at enabling people with a diagnosis of psychosis, living in the community, to participate in activities of everyday life:

1. To achieve a valid description of occupational therapy, with good utility, for a pragmatic RCT.

2. To explore the level of fidelity to occupational therapy and to test out a method of measuring fidelity.

3. To explore participants' adherence to occupational therapy and test out a method of measuring adherence.

4. To measure participation in activities of everyday life and identify a valid method of measuring participation, with good utility, for a pragmatic RCT.

5. To explore what indication of effect there is of occupational therapy, enabling individuals with a diagnosis of psychosis, living in the community to improve their participation in activities of everyday life.

6. To understand more about how occupational therapy enables people with a diagnosis of psychosis to participate in their activities of everyday life.

3.2 Study design

The long-term aim was to use a pragmatic RCT design to test the effectiveness of occupational therapy in practice. However there were a number of key uncertainties in the design of such an effectiveness study (see 3.1.3). When there are uncertainties with the design of a complex intervention, feasibility and

piloting methods are utilised before an explanatory study (MRC 2008). The merits of both pilot and feasibility studies were considered. Pilot trials use the same design and method as the subsequent larger main trial (Arain et al 2010, Charlesworth et al 2013). In contrast feasibility studies are designed to build the foundation for the planned intervention study (Tickle-Degnen 2013). Therefore a feasibility study was the most appropriate type of study because a suitable description of the intervention for clinical research did not exist and needed developing. Furthermore developing a feasibility study meant it was possible to explore the areas of uncertainty identified in the design because feasibility studies are conducted before a main study in order to answer the question "Can this study be done?" (National Institute for Health Research 2013).

It is acknowledged that both qualitative and quantitative approaches are likely to be needed for feasibility studies (MRC 2008). The different approaches are derived from particular philosophical understandings.

'Qualitative methods are linked to the constructionist or interpretist philosophical perspectives. Their focus is to interpret and construct how ordinary people observe and describe their lives in natural settings' (McLaughlin 2009, p.74).

In contrast quantitative methods are underpinned by postpositivist claims for developing knowledge, for example: cause and effect thinking and testing theories (Creswell 2003). The pragmatic perspective, as chosen for this study, is not committed to any one system of philosophy or reality, the inquirers draw liberally from both quantitative and qualitative assumptions (Creswell 2003). This is referred to as a mixed methods approach (Saks and Allsop 2007). It enables the different methods to complement each other and offers the potential to obtain a deeper understanding of people and events (Bowling 2009).

3.3 Study method

A carefully phased approach was planned to explore and test key design uncertainties following the principles for designing an effectiveness study of a complex intervention (MRC 2008). The study method had two key components: development of an occupational therapy intervention specification, which is reported in Chapter four and a feasibility study for a future pragmatic RCT (see Section 3.4 for feasibility study method).

The intervention specification (see Chapter four) was utilised within the feasibility study; however because of the extensive development work to establish an intervention specification that had face validity and utility for a RCT, this is dealt with in a separate chapter.

3.3.1 Service user and carer involvement

The researcher sought expert opinions and critiques to increase the validity of the study, see summary Table 3.2.

'A valid study is one that has collected and interpreted its data, so that the conclusions accurately reflect and represent the real world that was studied' (Yin 2011, p.78).

The Researching Occupation Participation Effectiveness (ROPE) group was a collaboration of people interested in fostering the development of effectiveness studies related to occupation and mental health; it had a wealth of experience in research, service user involvement work and occupational therapy. They were the steering group for this study, developed the initial research area for investigation and peer reviewed the progress of the study, providing constructive critiques of its validity. The study also utilised the Clinical Research

Footnote: *The ROPE group was disestablished once the study was being carried out*

Network (CRN) Mental Health FAST-R (Feasibility And Support to Timely recruitment for Research) Service, National Institute for Health Research (NIHR) which uses service user expertise to review research studies. The (CRN) Mental Health FAST-R reported that they found the study very interesting and were encouraged by the potential of this area of research (see Appendix 7).

Consultations/ discussions	**Summary of main response to recommendations/ changes made**
ROPE Group	
Discussion of research focus, 12/02/2013	Agreed that the research would focus on individuals with a diagnosis of psychosis, enabling results to potentially align to national guidelines e.g. National Institute for Health and Care Excellence guidelines (NICE).
Discussion regarding carrying out feasibility study rather than pilot, 03/09/2013	Progressed with feasibility study due to the number of key uncertainties in the design of a pilot study.
Discussion of Measures of Participation (MOP) work – led by Dr Katrina Bannigan, 24/09/2013	Pursued participation as the clinical outcome for the study and utilised the outcome measures from the MOP development work.
Discussion regarding the intervention specification and rationale for basing on existing evidence and using task analysis, 24/09/2013	Progressed with developing intervention specification as proposed and reported in Chapter four.
Review of study protocol, 23/05/2014	Study protocol was supported and finer review of utility in practice recommended.
Review of study protocol with occupational therapy professional lead (partner centre for study), 11/04/2014 & 04/07/2014	11/04/2014 Identification and enrolment process of potential participants discussed in detail and aligned to operational policy in partner centre. 04/07/2014 Calculations for optimum number of occupational therapists, research assistants and supervision discussed and agreed.
CRN Mental Health FAST-R, NIHR	
Reviewed study protocol and participant information sheets, 13/08/2014 (see Appendix 7)	Changes made to protocol and information sheets; reviewed with comments incorporated. Sent back for a second review.
Table 3.2 Summary of consultations with service users and carers and changes made	

Reviewed changes made to study protocol and participant information sheets, 04/09/2014 (see Appendix 8)	Final minor changes made to information sheets, including separate consent forms for the occupational therapists focus group.
Reviewed participant questionnaire and focus group conversation guide, 15/09/2014 (see Appendix 9)	Questions on participant questionnaire simplified as recommended.

Table 3.2 Summary of consultations with service users and carers and changes made (continued)

3.3.2 Ethical Issues

3.3.2.1 Ethical opinions and NHS permissions

A favourable ethical opinion for the study was given by the National Research Ethics Committee North West - Lancaster (REC reference: 14/NW/1426) on 3rd December 2014 (see Appendix 10). Research and Development approval was granted from Lancashire Care NHS Foundation Trust on 16th December 2014 (see Appendix 11) and permissions granted from Tees, Esk and Wear Valley NHS Foundation Trust on 22nd December 2014 (see Appendix 12).

3.3.2.2 The four principles of biomedical ethics

Beauchamp and Childress' (2009) Four Principles of Biomedical Ethics is one of the most widely used frameworks and offers a broad consideration of medical ethical issues (UKCEN (Clinical Ethics Network) 2015). These Four Principles are:

- respect for autonomy
- nonmaleficence
- beneficence
- justice

These provided a framework from which the ethical issues of the study were considered (Beauchamp and Childress 2009). The Principles are delineated

below and the key ethical issues of the study are identified related to each, further discussions regarding these are integrated throughout the chapter.

Respect for autonomy, personal autonomy has been defined as:

'…self-rule that is free from both controlling interference by others and limitations that prevent meaningful choice, such as adequate understanding' (Beauchamp and Childress 2009, p.101).

Achieving respect for autonomy was of particular concern when assessing potential participant's capacity (see Section 3.5.2.4) and gaining informed consent to take part in the study Section 3.5.2.5.

Nonmaleficence

'Nonmaleficence obligates us to abstain from causing harm to others' (Beauchamp and Childress 2009, p.150).

This was considered and discussed with regards to the potential harm from occupational therapy as an intervention and new information regarding its effectiveness (see Section 3.5.2.8) and from carrying out additional outcome measures (see Section 3.4.4.4.4 and 3.6.2). Also from the perspective of causing no harm from being involved in the occupational therapist focus group (see Section 3.6.8).

Beneficence

'The principle of beneficence refers to a statement of moral obligation to act for the benefit of others' (Beauchamp and Childress 2009, p.203).

It considers balancing the benefits of treatment against the risks and costs (UKCEN 2015). It was critical to ensuring the appropriateness of the method for the study question, to gain valid answers, whilst achieving minimum burden to the participants. This principle was the most widely applied, to the additional demands of being a research participant alongside receiving occupational therapy as an intervention (see Sections 3.4.1. and 3.4.4). Beneficence was

also considered with regards to achieving an appropriate sample size (see Section 3.5.1).

Beneficence was considered from the occupational therapists perspective of providing occupational therapy alongside the additional demands of being part of a clinical research study (see Section 3.4.2.1.2 and 3.4.4.4.2).

Justice

'Justice can be interpreted as fair, equitable, and appropriate treatment in light of what is due or owed to persons' (Beauchamp and Childress 2009, p.250). Particular aspects of the study that related to justice were: achieving an appropriate sampling strategy (see Section 3.5.1); fair and equal treatment to those who did not want to take part or who wanted to withdraw from the study (see Section 3.5.2.8). It was also applied for the scenario when participants needed/wanted to continue with occupational therapy after the study time period was achieved, see Section 3.4.2 for further discussion.

3.4 Feasibility study method

The purpose of carrying out the feasibility study was to explore how possible it would be to carry out a pragmatic RCT in the future? An explanatory approach was inappropriate to use at this point in time because of the extent of the methodological uncertainties (see Section 3.1.3). Fundamental to the process of developing and evaluating complex interventions is modelling the process and outcomes (MRC 2008). A before-after design was applied to model the processes and outcomes of an occupational therapy pragmatic RCT, without a control group. Using the before-after design, participants were exposed to the experimental/ independent variable (occupational therapy), and the dependent variable (participation) was measured before and after the intervention to

measure the effects of the independent variable (Bowling 2009). The before-after study embedded both study outcomes and measures (see Sections 3.4.4.1 and 3.4.4.2) and process outcomes and measures (see Sections 3.4.4.3 and 3.4.4.4) to answer the question: how possible would it be to carry out a pragmatic RCT? The study methods of using both study outcomes and process outcomes was partially replicated from, an occupational therapy feasibility study exploring the impact of occupational therapy in Parkinson's disease (Strukenboom et al 2012). This study led on to a full RCT of the effectiveness of occupational therapy in Parkinson's disease (Sturkenboom et al 2013).

The CONSORT 2010 Statement (Schulz et al 2010) was used to support robust reporting of this study, it provides guidance for reporting all RCTs using clear and transparent information on how to conduct methodology and report a study's findings. The earlier *CONSORT 2001 Statement* (Moher et al 2001) was extended to make it applicable for pragmatic trials (Zwarenstein et al 2008). Although this was not a pragmatic RCT, it was modelling the processes and outcomes for a pragmatic RCT, consequently these guidelines were also used where appropriate. The Transparent Reporting of evaluations with Non-randomized Designs *(TREND) checklist* is designed for reporting standards and of behavioural and public health intervention evaluations involving non-randomized designs and is meant to be consistent with the *CONSORT 2001 Statement* (Jarlais et al 2004). The *TREND checklist* was also utilised where appropriate.

Study protocol

The protocol for the feasibility study can be found in Appendix 13. The protocol for the feasibility study was titled the POINTER Study which is an acronym for

Participation…through Occupational INTervention Effectiveness Research. The protocol had all the key research documents for operationalising the study in practice. It followed the structure as recommended by the *SPIRIT 2013 Statement: Defining Standard Protocol Items for Clinical Trials* (Chan et al 2013). The guidelines outline the minimum content of a clinical trial protocol and whilst this was not an RCT, it was preparing for one; therefore it was deemed good practice to follow these guidelines for the feasibility study. To prevent duplication in the presentation of documents in the Appendix, the study documents that are embedded in the study protocol will be referred to as Appendix 13 and the page number will be given for each document being cited.

Structure of the method

The method first discusses the participants (see Section 3.4.1), extrapolating the inclusion and exclusion criteria and including the settings for the feasibility study. It defines the planned occupational therapy intervention (see Section 3.4.2) discussing the rationale for and describing the approach taken to recruit occupational therapists to provide the intervention for the study (see Section 3.4.2.1). Further to this it articulates the training and supervision provided for the occupational therapists, together with the reasoning for this. The hypothesis for the study is shared in Section 3.4.3. In Section 3.4.4 the outcomes and outcome measurement/ data collection tools used for the study are discussed and outlined, these are presented in two parts:

- Study outcomes (see Section 3.4.4.1) and outcome measures (see Section 3.4.4.2).
- Process outcomes (see Section 3.4.4.3) and process outcomes data collection tools (see Section 3.4.4.4)

The sample size and the sampling process are debated and defined in Section 3.5 and 3.5.1 respectively. In Section 3.5.2 the approach to recruiting and enrolling the sample is considered; the key roles and responsibilities of those involved are outlined (see Table 3.3). This section also deals with how: capacity was assessed; informed consent was ensured and gained and confidentiality maintained. Each of these aspects, are discussed in the context of the related ethical principles. Data collection processes are presented in Section 3.6 and how data security was maintained is discussed and outlined in Section 3.7. The chapter concludes with a discussion and description about the planned approach to analysing the findings of the feasibility study in Section 3.8 for both the participant and process outcomes of the study.

3.4.1 Participants

Pragmatic RCTs are characterised by broad eligibility criteria in contrast to explanatory trials which are typified by longer lists of exclusion criteria (Hotopf et al 1999, Thorpe et al 2009). The rationale for this different pragmatic approach, is that clinical services accept all comers; including broader groups of subjects and it enables the results to be more applicable to clinicians own circumstances (Hotopf et al 1999). The inclusion and exclusion criteria were developed in the context of appropriate eligibility criteria for a pragmatic RCT (Thorpe et al 2009).

3.4.1.1 Inclusion criteria

A summary of all of the inclusion criteria for the participants is given in Box 3.2. Each of the inclusion criteria for the participants is discussed in turn, including the rationale for the criteria decisions made.

Individuals over the age of 18 years, with no upper age limit and living in the community

No upper age limit was set at this reflected how the community mental health services functioned in both of the research centres i.e. service users may remain within the service rather than being transferred automatically to older adult services when they reach the age of 65 years. *The Mental Health Policy Implementation Guide, Community Mental Health Teams* (Department of Health 2001) recommends this service for working age adults and that age limits are determined in line with locally agreed protocols for transitions from adult to older adult services.

- Individuals over the age of 18 years, with no upper age limit and living in the community
- Individuals with a current primary diagnosis of psychosis (e.g. schizophrenia, schizo-affective disorder, psychotic depression or bipolar disorder)
- Individuals with dual diagnosis or physical/sensory disabilities were included.
- Individuals with mild to very severe occupational/ functional needs

Box 3.2 Summary of inclusion criteria

Individuals with a current primary diagnosis of psychosis (e.g. schizophrenia, schizo-affective disorder, psychotic depression or bipolar disorder)

This was determined according to the clinical diagnosis in the clinical notes. Additional assessments of the mental health symptoms of service users were considered; however these were discounted partly because pragmatic trials accept all participants who have the condition of interest (Thorpe et al 2009). Also from a beneficence perspective the gaining of detailed symptom profiles

(which was not a primary outcome of the study) was not greater than that achieved through minimising the participant burden of additional assessments.

Individuals with dual diagnosis or physical/sensory disabilities

The existence of co-morbidities is a feature of pragmatic RCTs (Thorpe et al 2009). Therefore participants could have a dual diagnosis or physical/ sensory disabilities; with the expectation that neither of these would be the primary diagnosis (See Box 3.3). This criteria, was also used in a pilot occupational therapy RCT for people with psychotic conditions in the community (Cook et al 2009).

Individuals with mild to very severe occupational/ functional needs

Occupational/ functional needs was a core part of the inclusion criteria, as it was highlighted in the systematic review Chapter two as lacking in the majority of studies in the review (see Section 2.4.3). In this study it was indicated initially by the use of the Health of the Nation Outcome Scale (HoNOS). The HoNOS is an outcome measure of health and social functioning of people with severe mental illness and is now the most widely used outcome measure in specialist mental health services in England (Royal College of Psychiatrists 2013). The HoNOS can be used to obtain a detailed characterisation of the clinical and social needs of the patient (Salvi et al 2005). Participants who scored two or more, on question 10 of the HoNOS were classified as meeting the initial eligibility criteria. This score indicated that they had a mild to very severe problem with activities of daily living; this reflected current practice.

3.4.1.2 Exclusion criteria

The exclusion criteria, was guided by the *PRECIS* (Thorpe et al 2009) and whilst co-morbidities are a feature of most pragmatic trials, this was considered

in conjunction with the need to have eligibility criteria that were strict enough to determine cause and effect. The exclusion criteria are summarised in Box 3.3, these were specified to support the diagnosis of psychosis being the primary diagnosis for the participants recruited into the study.

- Individuals with a diagnosis of an organic brain disorder or suspected organic cause to the psychosis
- Individuals with a primary diagnosis of substance misuse

Box 3.3 Summary of exclusion criteria

3.4.1.3 Settings

Eligibility criteria should be framed to show the degree to which they include typical participants, typical providers and settings (Thorpe et al 2009). The study recruited from adult mental health services, including adults from early intervention services in the North of England; this strategy for recruiting participants from a number of sources is in keeping with a pragmatic approach to eligibility (Thorpe et al 2009). Two centres were selected to carry out the research in two different NHS Trusts to support the validity of the results, as the results would not be atypical if drawn from more than one service. The site based in the North East (Centre one) was the Tees, Esk and Wear Valleys NHS Foundation Trust. This site was selected for the study because the occupational therapy professional lead was a core member of the ROPE group and volunteered to take part. The participants were recruited from the Community Mental Health Teams and Early Intervention for Psychosis Services. The site based in the North West (Centre two) was the Lancashire Care NHS Foundation Trust and this became part of the study because this is where the researcher was also the occupational therapy professional lead. Participants

were recruited from complex care and treatment teams and recovery teams, which combine community mental health and assertive outreach approaches. All participants were recruited from services that already provide occupational therapy as part of their service specification. Cook et al (2009) described occupational therapy taking place in community settings. Occupational therapy addresses practical skill difficulties, for example: budgeting, shopping, cooking, getting out and about, using public transport and using community facilities (Hughes and Parker 2014). The typical settings for these types of activities are service user's own homes and communities, including mental health team bases and these were the settings for the study.

3.4.2 Occupational therapy intervention

The ultimate aim was to carry out a pragmatic RCT. Therefore this study modelled the occupational therapy pathway (see Appendix 13, p.365) and outcomes, under the usual conditions in which it would be applied; as per pragmatic RCT guidance (Thorpe et al 2009). This was carried out without a control group. Therefore there were no additional resources utilised as this supports the pragmatism of the trial to apply the results to usual conditions of care (Zwarenstein et al 2008). The development of the occupational therapy intervention for use in this study is described fully in Chapter four.

It was important to apply the ethical principle of justice when considering the provision of occupational therapy in the study. Occupational therapy was provided routinely as part of the services where the study was conducted. Therefore those participants, who received occupational therapy during the study, were able to continue after the study intervention time period. This occurred when there was an assessed clinical need/ outstanding occupational need goals that the participant still wanted to work on.

3.4.2.1 Occupational therapists

An element of pragmatic trials is that the intervention is provided as it would normally be, in the usual settings (Zwarenstein et al 2008). This was maintained as far as possible with the use of occupational therapists already employed in the two NHS organisations to provide the intervention; the details of this are discussed throughout this section.

3.4.2.1.1 Eligibility criteria; occupational therapists

Qualified occupational therapists needed to be registered with the Health Care Professions Council (HCPC). The HCPC is the regulator of occupational therapists in the United Kingdom; it keeps a register of those who meet its standards for training, professional skills, behaviour and health (HCPC 2016). To support the pragmatic trial methodology the occupational therapists were already providing occupational therapy with people, with a diagnosis of a psychosis, living in the community at the time of the study. A summary of all the eligibility criteria is given in Box 3.4; occupational therapists also needed to be willing to take part in clinical research, which would include scrutiny of their clinical practice.

- Occupational therapist registered with HCPC
- Working at one of the NHS organisations acting as research sites
- Currently providing occupational therapy with people, with a diagnosis of psychosis, living in the community
- Willing to take part in clinical research

Box 3.4 Summary of occupational therapist eligibility criteria

3.4.2.1.2 Sample size; occupational therapists

The target recruitment number of occupational therapists for the study was calculated in the context of the study target sample size of 64 participants

(discussed in Section 3.5) and the length of time available for recruitment into the study was three months. It took into consideration that the all the occupational therapists would have existing caseloads, therefore they would only be able to recruit and provide occupational therapy to new participants on a graduated basis. Thought was also given to what would the best sample size to support fidelity? Together with acknowledging that it was likely that the more frequently the study protocol was used, the more likely it was to strengthen fidelity. Further to this was the pragmatic consideration given to the capacity to provide professional supervision to all those involved. Subsequently a realistic sample size for the occupational therapists was deemed to be eight (four occupational therapists from each research site). The aim was that each occupational therapist would be required to recruit eight participants each.

3.4.2.1.3 Recruitment; occupational therapists

Eligible occupational therapists in each centre were given the opportunity to be involved in the study via both of the occupational therapy professional leads. The researcher met with interested occupational therapists to explain the study, what would be involved and to answer any questions that they had. All occupational therapists who volunteered to be part of the study were enrolled.

3.4.2.1.4 Enrolment; occupational therapists

The researcher met individually with each occupational therapist who had volunteered to be involved, to explain the POINTER Study, using the *POINTER study occupational therapist information sheet* (see Appendix 13, p.391). The Information sheet was sent to potential occupational therapists prior to the enrolment conversation; where there was an opportunity to ask any questions that they had and reconsider before formally consenting to being part of the

study. Written consent for being an occupational therapist in the study was achieved through using the *POINTER study occupational therapist consent form* (see Appendix 13, p.395). The focus group was consented to separately by the occupational therapists using the *Occupational therapists focus group consent form* (see Appendix 13, p.396).

3.4.2.1.5 Training; occupational therapists

The occupational therapists were given a half day training session on how to follow the *POINTER study protocol* (Appendix 13). Further training was given alongside other people contributing to the study; this is explained in more detail in Section 3.5.2.1. This was provided to support fidelity to the protocol and particularly the accurate reporting of data about what was provided using the *POINTER study occupational therapy intervention log* (Appendix 13, p.399). The aim was for occupational therapists to start using this during a 'run-in' period for a month prior to the study, before formal recruitment to the trial, to ensure the intervention was being provided effectively and recorded accurately (Campbell et al 2000).

3.4.2.1.6 Supervision; occupational therapists

It was planned that each centre would have an occupational therapy clinical specialist, from that centre trained in use the *POINTER study protocol* (Appendix 13). This person would provide monthly professional supervision for the occupational therapists in relation to their POINTER study occupational therapy caseload and also carry out the fidelity checks (discussed in Section 3.6.4). All occupational therapists continued to receive their regular professional supervision. If any particular issues with regards to malpractice or untoward incidents with the occupational therapists were raised, these would have been

discussed and addressed in the professional supervision provided in accordance to the occupational therapy *Code of Ethics and Professional Conduct* (College of Occupational Therapists 2015) and the HCPC regulations (HCPC 2016).

3.4.3 Hypotheses

The ability of a theory to be disproved distinguishes a scientific theory from a belief, stressing the virtues of falsification and is known as the hypothetic-deductive method (Bowling, 2009). The feasibility study was not adequately powered to test hypotheses and generalise the results. However, it was important to develop a working hypotheses in conjunction with the study objectives, thus supporting the analysis of the findings and the development of hypotheses for a future pragmatic RCT. This was done as part of developing the intervention specification in Section 4.4.2.

The hypotheses developed were:

Hypothesis 1

Occupational therapy is associated with enhanced participation with activities of everyday life for individuals with a diagnosis of psychosis, living in the community.

Hypothesis 2

Enhanced participation with activities of daily life is positively associated with health-related quality of life for individuals with a diagnosis of psychosis, living in the community.

3.4.4 Outcomes and outcome measurement

As is typical of feasibility studies, this study had both study outcomes and process outcomes, as introduced in Section 3.4. This replicated an approach used in a randomised controlled feasibility study of the impact of occupational therapy in Parkinson's disease by Sturkenboom et al (2012), where a process evaluation was carried out alongside the effect study. The study successfully led on to a randomized controlled trial (Sturkenboom et al 2013). The study outcomes and process outcomes for this feasibility study are shown in Table 3.3; these relate to the objectives of this thesis (see Section 3.1.4.2).

The study outcomes primarily concern the participant outcomes related to the hypotheses (see Section 3.4.3), these are discussed in Section 3.4.4.1; the related outcome measurement tools are debated and outlined in Section 3.4.4.2.

Study outcomes	Process outcomes
• Primary and secondary outcomes • Details of the occupational therapy provided, including fidelity and adherence ratings	• Validity of the description of occupational therapy • Utility of the method to measure fidelity • Utility of the method to measure adherence • Utility of the method to measure participation in activities of everyday life • How occupational therapy enables people with a diagnosis of psychosis to participate in activities of everyday life?

Table 3.3 Study outcomes and process outcomes

The process outcomes are discussed in Section 3.4.4.3; focussing on exploring the key uncertainties identified in the design of an effectiveness trial for occupational therapy in this area of practice (see Section 3.1.3). Whilst the details about the occupational therapy provided are recognised as study

outcomes, the data collection tools for this will be articulated in 3.4.4.4, together with the process outcomes data collection tools.

3.4.4.1 Study outcomes

This section concentrates on the participant outcomes. The other fundamental study outcome is the details about the provision of occupational therapy for the study, which will be provided using the *(TIDieR) checklist* (Hoffmann et al 2014).

3.4.4.1.1 Primary outcome: participation in activities of everyday life

The hypothesis (Section 3.4.3) theorises that occupational therapy is associated with enhanced participation in activities of everyday life for individuals with a diagnosis of psychosis, living in the community. Therefore participation in activities of everyday life was the identified as the primary outcome of the feasibility study. As discussed in Section 1.3.4 there was no consensus about how participation was conceptualised (Khetani and Coster 2007). Therefore a systematic literature review and concept analysis was used to develop a definition for this study focussed on mental health. The definition created was: 'Participation occurs when an individual is involved in activities, within the context of their life, which provides that person with a sense of engagement'.

3.4.4.1.2 Secondary outcomes

The secondary outcomes were:

- Health-related quality of life
- Self-reported experience of occupational performance and satisfaction with occupational performance

The secondary outcomes are connected to the primary outcome with occupational therapy theory, as discussed when developing and evaluating the

occupational therapy intervention specification in Section 4.4.2. The foundational beliefs of occupational therapy are based on the principles of occupation and participation, and the importance of these to the health and well-being of the individual and society (Baum 2003, Law 2002, Vessby and Kjellberg 2010, WFOT 2012). Therefore enhanced participation would be expected to be associated with health and well-being, subsequently health-related quality of life was a secondary outcome; this is reflected in hypothesis two. The CRN mental Health FAST-R appreciated the fact that this study encompassed improving quality of life measures. They felt it is a key part of recovery and good activity in building the evidence base (see Appendix 9).

The primary goal and outcome of occupational therapy is to enable people to participate in the activities of everyday life, other significant outcomes include satisfaction derived from occupational performance as described in the World Federation of Occupational Therapists POSITION STATEMENT: occupational therapy 2010 (WFOT 2012). Self-reported experience of occupational performance and satisfaction with occupational performance was included as a secondary outcome, as it is an indicator used in occupational therapy practice of enhanced participation with activities of everyday life.

3.4.4.2 Study Outcome measures

In RCTs a statement is required about how the effect of the intervention will be measured (Saks and Allsop 2007). Part of the process of developing and evaluating complex interventions is choosing suitable outcome measures (MRC 2008). In order to test a hypothesis empirically, an explanation needs to be given about what can be used to measure (operationalise) all the concepts contained within the hypothesis (Bowling 2009). An outcome measure is a tool

to measure or quantify change; this measurement can demonstrate the effectiveness of an intervention for individuals (COT 2012). In effectiveness studies, outcome measures are administered before the intervention and after the intervention to assess change in the outcomes/ dependent variables. This enables analysis of the magnitude of change between the baseline and follow-up measurements (Bowling 2009).

In effectiveness studies there are primary and secondary outcome measures (CONSORT 2010). The primary outcome measure represents the greatest therapeutic benefit and should be pre-specified (CONSORT 2010). The primary outcome was pre-specified in Section 3.4.4.2.1 and the secondary outcomes were discussed and outlined in Section 3.4.4.2.2. The aim of the outcome measure selection in this study was to measure the primary and secondary outcomes identified in Section 3.4.4.1, whilst balancing that with achieving beneficence towards the participants. The primary and secondary outcomes and measures are presented in Table 3.4.

Outcomes	**Primary outcome measure**	**Secondary outcome measures**
Participation in activities of everyday life *(primary)*	Time Use Survey	Participation Scale (P-Scale)
		Utrecht Scale for Evaluation of Rehabilitation Participation (USER-P)
Health-related quality of life *(secondary)*	-	Short Form-36v2 Health Survey (SF-36v2)
Self-reported experience of occupational performance and satisfaction with occupational performance *(secondary)*	-	Canadian Occupational Performance Measure (COPM)

Table 3.4 Primary and secondary outcomes and measures

3.4.4.2.1 Primary outcome measure

This was a feasibility study and part of the purpose was to identify the primary outcome measure for a future pragmatic RCT. The primary outcome for the study was participation in activities of everyday life, the definition being used was: 'Participation occurs when an individual is involved in activities, within the context of their life, which provides that person with a sense of engagement'. This definition was used to review the content validity of different measures of participation relevant to mental health. The outcome of this piece of work concluded that there was no reliable and valid measure of participation that could be used as the primary outcome measure for this study. However the Participation Scale (P-Scale) and the Utrecht Scale for Evaluation of Rehabilitation-Participation (USER-P), were identified as having the greatest face validity and utility in all of the measures of participation reviewed. In such circumstances the criterion validity can be tested; that is the degree of convergence or divergence with a tried and tested indicator of the concept (Saks and Allsop 2007). This is carried out by examining its relationship with a robust measure of the primary outcome or one of its constructs:

> 'For example, there is strong evidence of a positive relationship between health status and affluence/ deprivation. Thus, the development of an indicator of deprivation could have its validity tested by examining its relationship with a robust measure of health status' (Saks and Allsop 2007, p.180).

For the purposes of this study, it is important to note that there is a recognised association between engagement in daily occupations and time use. Bejerholm et al (2006) explored this through the means of time-use diaries. 'Time use' i.e. an individual's involvement in activities, is a key construct of participation, therefore changes in 'time use' would be expected to have a positive correlation with participation, as it is one of its constructs. 'Time use' has been measured

using the *UK 2000 Time Use Survey (TUS)* (Short 2006). This was developed by the Office for National Statistics to measure the amount of time spent by the United Kingdom population, on various activities and was designed, where possible to provide results comparable with other European studies (Short 2006).

Time Use Survey

An adapted version of the *UK 2000 TUS* (Short 2006) was used in a cognitive behavioural study with individuals with a diagnosis of psychosis, the measure consisted of a semi-structured interview in which participants were asked about how they had spent their time over the past month (Fowler el al 2009). The study recruited 77 participants with a diagnosis of psychosis and no issues regarding the utility of the adapted version of the *UK 2000 TUS* (Short 2006) were identified (Fowler et al 2009). Therefore the primary outcome measure for the indication of effectiveness of occupational therapy for this study was an adapted version of the *UK 2000 TUS* (Short 2006). Copies of the survey by Fowler et al (2009) were not available so the *UK 2000 TUS* (Short 2006) was adapted in a similar way. The same two summary measures were used: hours in 'Constructive Economic Activity' (calculated as the sum of hours per week over the past month spent in work, education, voluntary work, housework and chores and childcare) and hours in 'Structured Activity' (calculated as the sum of hours per week over the past month spent in constructive economic activity, and also includes voluntary and structured leisure activities, sports and hobbies) (Fowler et al 2009). This analysis about how best to measure the primary outcome of the study was presented to the ROPE group and the approach was affirmed.

3.4.4.2.2 Secondary outcome measures

The secondary outcome measures are summarised in Table 3.4. The participation outcome measures are described in Section 3.4.4.2.3. Measures for health-related quality of life are critiqued and then described in Section 3.4.4.2.4. Thirdly two measures for self-reported experience of occupational performance and satisfaction with occupational performance are critiqued in Section 3.4.4.2.5 to choose the appropriate measure for the study.

3.4.4.2.3 Measures of participation

The outcome measures of participation supported the measurement of the primary outcome as discussed in Section 3.4.4.2.1. The two measures of participation, were the Participation-Scale (P-Scale) and the Utrecht Scale for Evaluation of Rehabilitation Participation (USER-P). This Section describes how the outcome measures are administered and what specifically each measure measures.

The Participation Scale

The Participation Scale (P-Scale) is an interview based scale that measures the severity of participation restriction; it grades participation restriction from no significant restriction to extreme restriction (Brakel 2010). A score of 12 and below is considered to be ‘normal’ (not having significant participation restrictions), the higher the score the more severe the restrictions to participation (Brakel 2010).

Utrecht Scale for Evaluation of Rehabilitation Participation

Utrecht Scale for Evaluation of Rehabilitation Participation (USER-P) assesses three aspects of participation: frequency, experienced restrictions and satisfaction (Zee et al 2010). The frequency of participation is measured in two

parts, that is; ‘vocational activity’ and ‘leisure and social activity’ (Zee et al 2010). It is a questionnaire about the individuals daily life, asking questions about how much time is spent working, studying and attending to household duties and how often certain activities are undertaken. The higher the total scores the higher the participation, the satisfaction with participation and the less participation restriction (Zee et al 2010).

3.4.4.2.4 Measure of health-related quality of life

Issues have been explored with measuring health-related quality of life with people with severe and enduring mental illness (Atkinson et al 1997). Reininghaus and Priebe (2012) conducted a review focussed specifically on self-reported outcomes in psychosis. The quality of life measures reviewed included EQ-5D, WHOQOL and SF36; short measures with clinical relevance and sufficient psychometric properties were preferred. It was recommended that future research should optimise the validity and measurement precision of patient reported outcomes (PROs), while reducing assessment burden (Reininghaus and Priebe 2012).

McDowell (2006) in his compendium of health measures provides an overview of each measure, with a summary of the existing psychometric literature and a commentary on the measure. Each measure in a section, e.g. general health measurements and quality of life scales, are compared to the other measures so that the reader can assess the difference in the quality of the measures in that section. There was no information regarding the WHOQOL (and the WHOQOL-BREF was not listed). The EQ-5D (5 minutess) and SF-36 (5-10 minutes) had a similar assessment burden with regards to time taken to administer. Both were assessed as conceptually sound (where as WHOQOL-

BREF focuses on Hybrid satisfaction/ role functioning; however McDowell considers it a QOL measure and it does not score as high on validity as the other two). The best was the SF 36 on every quality criteria for assessing a measure (McDowell 2006). Therefore this was the measure chosen to be used in the study.

The Short Form – 36 Health Survey (SF-36 v2)

The SF-36v2 takes approximately five to ten minutes to complete for the adult population (McDowell 2006). It contains 36 items which are used to measure eight domains of health-related quality of life (HRQOL) and these are:

- Physical functioning (PF)
- Role-physical (RP)
- Bodily pain (BP)
- General health (GH)
- Vitality (VT)
- Social functioning (SF)
- Role emotional (RE)
- Mental health (MH)

In addition to these it also measures Self-evaluated transition (SET) where the respondent compares their health now to one year ago (Maruish 2011). From the eight health domain scales two summary measures are created, which are:

- Physical component summary (PCS) measure
- Mental component summary (MCS) measure

Normative data is available for the healthy population of the United States (Maruish 2011).

‘ Low scores on the PCS measure indicate limitations in physical functioning, limitations in role participation due to physical problems, a high degree of bodily pain, and/or poor general health’ (Maruish 2011, p.17).

Whereas the interpretation of the MCS is stated as;

‘For the MCS measure, a very low score is indicative of frequent psychological distress, social and role-disability due to emotional problems, and/or poor general health’ (Maurish 2011, p.18).

3.4.4.2.5 Patient reported outcome measure

The PRECIS states that outcomes should be clinically meaningful to the study participants (Thorpe el al 2009). The importance of Patient Reported Outcome Measures (PROMs) is becoming more recognised, PROMs are a record of the quality and effectiveness of care as perceived by the patients (COT 2012). In pragmatic trials outcomes are assessed under the usual conditions of practice (Thorpe et al 2009). In the two centres there were two main PROMS being used in practice; the Occupational Self Assessment (OSA) and the Canadian Occupational Performance Measure (COPM), both of which are standardised occupational therapy outcome measures. These outcome measures were considered for use in the study to measure occupational performance from the participant’s perspective. The OSA had been indicated to have preliminary validity and reliability (Kielhofner and Forsyth 2001). The OSA measures competence and values related to predefined aspects of occupations and carrying them out related to ‘Myself’. The measure did not enable participants to define their own specific occupational performance problems and therefore the COPM was chosen for use in this study.

The Canadian Occupational Performance Measure (COPM)

The COPM measures self-reported experience of occupational performance and satisfaction with that performance using a scale of 1-10 (Roberts et al 2008). A change in rating of occupational performance or satisfaction with

occupational performance of two points or more is considered to be clinically significant (Law et al 1998). Importantly the COPM has been shown to have utility with individuals with a diagnosis of schizophrenia. In a study conducted with nine clients with schizophrenia, who received community-based occupational therapy the COPM was carried out before and after each individual had received a 12 week period of occupational therapy (Cresswell and Rugg 2003). The COPM was sensitive enough to show clinically significant and quantifiable change in participant's occupational performance and satisfaction over time (Cresswell and Rugg 2003). The COPM was also used successfully by Sturkenboom et al (2012) in an occupational therapy randomised controlled feasibility study with people with a diagnosis of Parkinson's disease.

Ethical aspects of outcome measure selection

The ethical principle of nonmaleficence was applied in relation to the types and numbers of outcome measures selected for use with the participants. From a beneficence perspective the extra burden from completing some additional assessments before they commence occupational therapy and after they have been discharged or at six months was also a consideration. Attempts were made to keep these to an absolute minimum whilst balancing this with ensuring that all the information that was required was gathered during the research process. Thus the potential benefits to the population as a whole, with respect to gaining more knowledge about the effectiveness of occupational therapy to enable individuals with a diagnosis of psychosis, living in the community, to improve their participation and the need to minimise the burden on participants.

3.4.4.3 Process outcomes

Understanding processes is an important part of evaluating complex interventions (MRC 2008). It is recommended that process evaluations of the study are conducted to the same high methodological standards and reported as thoroughly as the evaluation of outcomes (Roen et al 2006 cited in MRC 2008, p.12). The process outcomes are outlined in Table 3.5, together with a summary of which data collection tool contributed to collecting data for each of the outcomes.

	Data collection tools (√ = data collection for process outcome)				
Process outcomes	Qqrl	Otil	Fc	Pq	Otfgcg
Valid description of occupational therapy	√	√	√	√	√
Utility of the method to measure fidelity	√	√	√	√	√
Utility of the method to measure adherence	√	√	√	√	√
Utility of the method to measure participation in activities of everyday life	√	√		√	√
How occupational therapy enables people with a diagnosis of psychosis to participate in activities of everyday life?		√	√	√	√

Table 3.5 Data collection tools used for each process outcome

3.4.4.4 Process outcomes, data collection tools

Different tools and methods of data collection were chosen and developed to collect the process data; this is consistent with the pragmatic theoretical perspective and a mixed methods approach. This triangulated methods

approach contributes to minimising research bias and enhances the validity of the results by testing the consistency of the findings obtained from different methods (Bowling 2009). The rationale for and the process of development for each of the data collection tools are discussed and described in this section, inclusive of the following:

- Questions, queries and resolutions log (Qqrl) (see Appendix 13, p.398)
- Occupational therapy intervention log (Otil) (see Appendix 13, p.399)
- Fidelity checklist (Fc) (see Appendix 13, p.405)
- Participant questionnaire (Pq) (see Appendix 14)
- Occupational therapist focus group conversation guide (Otfgcg) (see Appendix 15)

The method for measuring the actual overall fidelity and adherence to the occupational therapy intervention is outlined in Table 4.5; however the tools used for collecting this data are outlined in this section.

3.4.4.4.1 Questions, queries and resolutions log

The purpose of the Questions, queries and resolution log (see Appendix 13, p.398) was to capture questions and queries about the study and to resolve them as the study progressed. The log recorded: the date; occupational therapist identification number; question/ query and the resolution.

3.4.4.4.2 Occupational therapy intervention log

This was designed for the occupational therapists to complete after each occupational therapy session and a copy can be found in Appendix 13, p.399. It was developed in the context of the ethical principle of beneficence i.e. keeping the additional burden to the occupational therapists to a minimum, as it was a

pragmatic study and they already had a caseload and this was balanced with gaining the information needed. In a RCT study protocol for the effectiveness of occupational therapy in Parkinson's disease by Sturkenboom et al (2013) a process evaluation summary sheet was used to collect this data; a similar format was used for this study. The key information collected through the occupational therapy log is summarised in Box 3.5. Where possible closed questions were used as the purpose was to quantify the occupational therapy provided, the majority of these related to information required for the *TIDieR checklist* (Hoffmann et al 2014). Occupational therapists also had the capacity to record any instances where they were providing occupational therapy that was not able to be captured using the occupational therapy objectives and key activities. Two open questions were used to generate information about what factors facilitated and hindered the occupational therapy intervention? This gave the occupational therapists space to provide the views and opinions that they wanted.

- Nature of contact (occupational therapy and/or other)
- Location
- Duration of contact
- Occupational therapy key activities
- Participant adherence to occupational therapy
- Other non-occupational therapy interventions provided
- Occupational performance problems and therapy goals
- Occupational therapy outcome measure scores
- Record of overall occupational therapy effectiveness
- What facilitated and hindered the occupational therapy intervention
- Information about participants who wish to withdraw (if they chose to withdraw).

Box 3.5 Key information collected in the occupational therapy log

3.4.4.4.3 Fidelity checklist

This was designed to monitor and support fidelity to the POINTER study occupational therapy provided (see Appendix 13, p.405). The checklist reflects 'Section B: Occupational therapy key activities' of the *POINTER study occupational therapy intervention log.* It has a corresponding column which enables the information given by the occupational therapist to be checked against evidence in the participant's case-notes.

3.4.4.4.4 Participant questionnaire

Nonmaleficence with regards to participant burden was considered when deciding the best method of collecting data about participant's experiences. This was in conjunction with the ethical principle of beneficence which was applied regarding the amount of outcome measures being carried out, whilst gaining the information needed consequently a questionnaire approach was chosen. Sturkenboom et al (2012) also used a questionnaire post-intervention to capture patients and caregivers experiences with the intervention, largely made up of closed questions to minimise participant burden. A similar questionnaire design was used for this study (see Appendix 14). The questionnaire was reviewed by the CRN fast-track service (see Appendix 9). Adjustments were made to the questionnaire design, in relation to the comments given; Box 3.6 identifies the key question areas.

- Satisfaction with occupational therapy
- Relationship with the occupational therapist
- Effectiveness of the occupational therapy
- Adherence to occupational therapy
- Enablers and hurdles to participation in activities of daily life (open questions)
- Satisfaction with the outcome measures (open questions)

Box 3.6 Key question areas in the Participant questionnaire

3.4.4.4.5 Occupational therapist focus group conversation guide

This was designed to explore the; occupational therapists' experiences of the occupational therapy pathway; the utility of the *Occupational therapy intervention log* and how occupational therapy had enabled participants to improve their participation in activities of daily life (see Appendix 15). An inductive approach was utilised because information needed to be generated to answer the research objectives. A broad conversation guide structure of open ended questions was developed, this was also critiqued by the CRN fast-track service (see Appendix 9); consequently some amendments were made.

3.5 Sample size

Feasibility studies are not expected to have sample sizes large enough to adequately power statistical null hypothesis testing (Tickle-Degnen 2013). As the aim of the study was to explore how feasible it would be to carry out a future multi-centre RCT, part of the planned data analysis was to consider the centres independently to enable any differences in practice to be identified and learnt from. The suggested target sample size for a pilot study is 30 participants in the intervention arm (Lancaster et al 2002). The study aimed to recruit 64 participants, to allow for a dropout rate of approximately six percent; this aimed to achieve a final sample of no lower than 60 participants (30 participants in each centre). This potential drop-out rate was informed by the Cook et al (2009) study which was a pilot randomised controlled trial of occupational therapy for people with psychotic conditions and had a five percent dropout rate and the study by Fowler et al (2009) which was a single-blind randomized controlled trial for improving social recovery in psychosis, which had an eight percent drop out rate.

3.5.1 Sampling

It is acknowledged that feasibility studies for randomised controlled trials may themselves not be randomised (Arain et al, 2010 p.4). This study was not randomised due to the number of methodological uncertainties that were being explored (see section 3.1.3). Also when applying the ethical principle of beneficence the methodological benefit of having a control group was not greater than the cost of creating additional participant burden by increasing the sample size. The aim of a sampling strategy was to achieve a representative sample of the target population from which it was drawn (Kendall 2003). Selection bias of the participants was minimised by clearly defining the inclusion and exclusion criteria (see Section 3.4.1.1 and 3.4.1.2). The ethical principle of justice supports the decision to use routine NHS referral systems. That is to offer involvement in the study to all those individuals who met the criteria, and who had been assessed as having the capacity to be involved in the research, enabling the opportunity of involvement to be fair. Consecutive sampling from the accessible population is recommended as the best design to achieve a representative sample of the target population (Kendall 2013). The ethical principle of respect for the autonomy of the participants was applied to minimise the bias created by non-response; supported by making the study valid, transparent and easy to be involved in for the participants. This was approached by using the ROPE Group and the CRN Mental Health FAST-R service to review the study and associated documents (see Appendix 7, 8 and 9).

3.5.2 Recruiting and enrolling the sample

This section discusses and outlines how participants were recruited and enrolled into the study. It outlines the roles and responsibilities of all those involved in the study (see Section 3.5.2.1). It examines how confidentiality was maintained (see Section 3.5.2.2). The enrolment process is presented in Illustration 3.1, the process is outlined including delineation about how participants capacity was assessed (see Section 3.5.2.4) and informed consent is gained (see Section 3.5.2.5). The process of screening for participants occupational/ functional needs is extrapolated in the context of pragmatic RCT guidelines (see Section 3.5.2.6). How potential risks, from home and community visits was managed is dealt with in Section 3.5.2.7. Lastly how new information was monitored regarding the effectiveness of the intervention is discussed and linked to the ethical principle of justice.

3.5.2.1 Roles and responsibilities

The sample was recruited and enrolled with the support of the people shown in Table 3.4; this gives a summary the roles and responsibilities of those involved and the training provided in relation to these. As all those involved in the enrolment process were NHS staff, all were bound by NHS Trusts policies and procedures regarding confidentiality.

The occupational therapists (see Section 3.4.2.1) and the occupational therapy clinical specialists (see Section 3.4.2.1.6) were introduced earlier in this chapter. The research assistants were also occupational therapists from each of the centres, who volunteered to be involved to as part of their continuing professional development. The local collaborator was identified through the process of applying for ethical permission (see Section 3.3.2.1) and also

provided support and supervision for the research assistants. All of the people in the clinically focussed research study roles were provided with the training outlined in Table 3.6. The training regarding the study protocol included what to do and who to contact if there were concerns about confidentiality and included appropriate training about data protection and security.

Roles	**Responsibilities**	**Training provided as part of POINTER**
Occupational therapists	Screened for occupational need and obtained verbal informed consent for occupational therapy and to be a participant in the study.	Good Clinical Practice (GCP) - online training (NIHR CRN 2016) How to complete outcome measures How to take informed consent. *POINTER study protocol*
Research assistants	Obtained written consent and carried out baseline and post-intervention outcome measures.	
Occupational therapy clinical specialists	Provided monthly professional supervision. Logged any questions, queries and resolutions.	
Local collaborator	Support and supervision to research assistants.	
Research administrator	Securely filing and saving data provided. Providing participant registration numbers.	Good Clinical Practice (GCP) – online training
Care co-ordinator	Assessed participants capacity	*POINTER study consultant/ staff information sheet* (Appendix 13, p.387)
Consultant Psychiatrist		

Table 3.6 Roles and responsibilities with enrolment process

Additionally the research administrator also carried out the Good Clinical Practice (GCP) online training (NIHR CRN 2016). GCP is described as:

> Good Clinical Practice (GCP) is the international ethical, scientific and practical standard to which all clinical research is GCP training conducted. Compliance with GCP provides public assurance that the rights, safety and wellbeing of research participants are protected and that research data are reliable (NIHR CRN 2016, p.4).

The consultant psychiatrists and care co-ordinators had the study explained to them using the *POINTER study consultant/staff information sheet* (Appendix 13, p.387).

3.5.2.2 Confidentiality

There is always the risk of having to breach confidentiality. It was made clear to participants in the *information sheet* (Appendix 13, p.377) and the *informed consent form* (Appendix 13, p.385) that if they should provide any information which indicates that they may be a risk to themselves or others, or that harm has been caused to another person or persons, that confidentiality will be broken.

3.5.2.3 The POINTER Study enrolment process

The enrolment process is represented in Illustration 3.1 and was carried out by the occupational therapists, research assistants and a research administrator (all separate to the main researcher); the researcher supervised the process with the support of the local collaborators. The central boxes demonstrate the step by step process to enrol a participant into the study. The boxes on the right indicate the associated POINTER study forms (Appendix 13, p.377-p.405) and the studies master file and database (see Section 3.7.2).

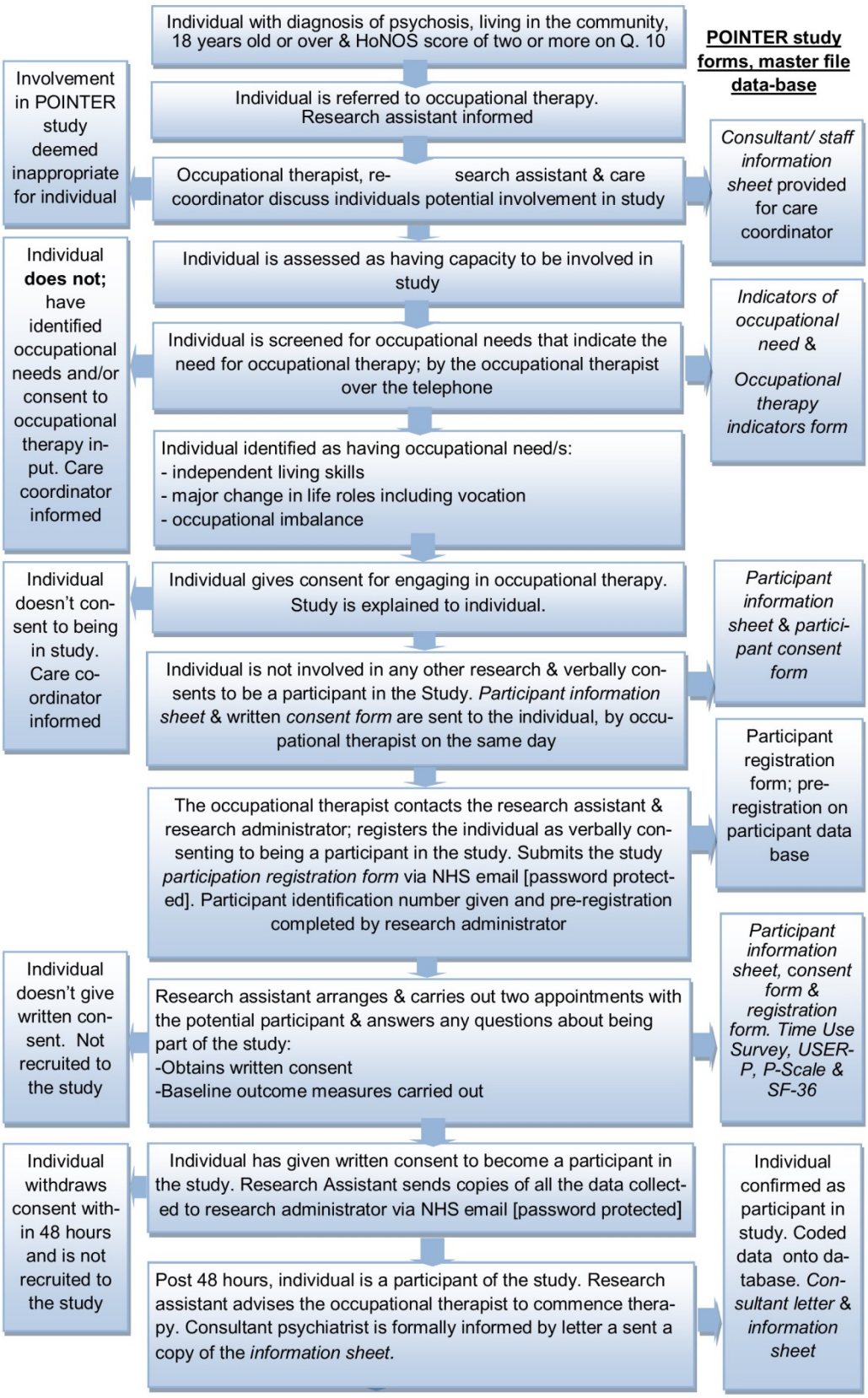

Illustration 3.1 POINTER Study enrolment process

The enrolment process and associated documents were reviewed by CRN Mental Health FAST-R service (see Appendix 7 and 8) and, approved by the REC (see Appendix 10). The boxes on the left indicate the points at which it would be inappropriate for the participant/ potential participant to continue in the POINTER Study.

3.5.2.4 Assessing capacity

Participants who had been identified as potentially eligible to take part in the study were assessed by their care coordinator, occupational therapist and research assistant, to make a judgement about their capacity to participate in the study.

> 'For the purpose of the Mental Capacity Act 2005: a person lacks capacity in relation to a matter if at the material time he is unable to make a decision for himself in relation to the matter because of an impairment of, or a disturbance in the functioning of, the mind or brain' (Great Britain. Parliament 2005, part 1, section 2, cited in COT 2015, p.ix).

Whilst respecting the autonomy of the individual to make their own decisions, there was an ethical consideration to ensure that each participant had the capacity to do so. When the participant was assessed as having capacity, the process of gaining informed consent for taking part in the study could progress.

3.5.2.5 Gaining informed consent

> 'Informed consent is an ongoing agreement by a person to receive treatment, undergo procedures or participate in research after risks, benefits and alternatives have been adequately explained to them. Informed consent is a continuing requirement. Unless restricted by mental health and/or mental capacity legislation, it is the overriding right of any individual to decide for himself (herself) whether or not to accept intervention' (COT 2015, p.19).

Informed consent was important to the study because the participants in the study needed to be fully aware of what they were consenting too, otherwise consent is not informed and therefore not legally given. This is again in the

realms of the ethical element of respecting the autonomy, by enabling the individual to make reasoned and informed decisions.

The eligible participants had the study explained to them by the occupational therapist over the telephone, where verbal consent could be given. However participants had at least three days to decide if they wanted to be part of the study. The participants who gave verbal consent were provided with the *POINTER study participant information sheet* (Appendix 13, p.377). When visited by the research assistant participants were given the opportunity to ask any questions they had, about what being part of the study would mean for them. Written informed consent was obtained from participants by the research assistant using the *POINTER study participant consent form* (Appendix 13, p.385). After this process participants had a further 48 hours, when they could change their mind, before the study commenced.

If individuals did not adequately understand verbal explanations or written information given in English, or if individuals had special communication needs, reasonable provisions were planned to be made. In such circumstances, assessment of communication needs would be assessed on an individual basis. If an individual was eligible for the study and there were some communication difficulties, everything would be done to make it practically possible for them to be part of the Study, as it would if they were a being treated as a patient in the NHS. This is cognisant with pragmatic RCT criteria (Zwarenstein et al 2008).

3.5.2.6 Screening for occupational need

Individuals with mild to very severe occupational/functional needs were part of the inclusion criteria for the study (see Box 3.2). This was initially indicated by the use of the HoNOS (Royal College of Psychiatrists 2013).

As part of the enrolment process the participants were contacted by the occupational therapists and this was planned to be via the telephone. During the conversation the individual's occupational needs were screened for occupational therapy. *The Indicators of occupational need* (see Appendix 13, p.381) and the *Occupational therapy indicators form* (see Appendix 13, p.383) guided this process; both used routinely in practice in Lancashire Care NHS Foundation Trust. This is in line with pragmatic RCT guidance which advocates for the intervention to be provided in the usual conditions in which it is applied (Thorpe et al 2009). The participants were offered occupational therapy if there were identified occupational need/s in any of the following; independent living skill difficulties; major change in life role, including vocational and/ or occupational imbalance. This criteria within the *Indicators of occupational need* form was based on *Defining occupational therapy as a complex intervention* (Creek 2003) and *An occupational perspective of health* (Wilcock 2006).

3.5.2.7 Managing potential risks from home and community visits with participants

The research assistants and occupational therapists who carried out assessments in participants own homes or the community, carried these out in accordance with the Tees, Esk and Wear Valley NHS Foundation Trust's or Lancashire Care NHS Foundation Trust policies relating to home visiting and personal safety. Additional support and supervision was available, should the research assistants or occupational therapists experience any distress from talking to participants about their individual circumstances.

3.5.2.8 New information

Nonmaleficence was expected from the occupational therapy interventions**.** However it was the researcher's duty of care, to regularly review the literature on the effectiveness of occupational therapy in this area of practice. In the event of robust research being published which described there being little or no effect for participants as a consequence of the intervention; this would have been reviewed with the research team. If it was relevant to the study's interventions, participants would have been notified. If this happened members of the research team would tell each participant and discuss whether they should continue in the study. If they decided not to carry on it would be important, to consider it from the ethical principle of justice and therefore the participant would continue to receive all other care. It would be made clear that their standard of care would not be affected in any way. If they decided to continue in the study, they would be asked to sign an agreement outlining the discussion.

3.6 Data collection process

This section delineates the data collection process, it first describes how the written consent and demographic data was collected from participants (see Section 3.6.1) and then outlines the process of collecting the baseline and post-intervention outcome measures; which was carried out by research assistants (see section 3.6.2). It details how information about what occupational therapy was provided, was collected throughout the study (see Section 3.6.3) and the process for monitoring and supporting fidelity to this (see Section 3.6.4). The *Questions, queries and resolutions log* was used throughout the study (see Section 3.6.5). The evaluation with participants about their experiences and the effectiveness of occupational therapy is collected through the *Participant questionnaire* (see Section 3.6.6). The data collection process regarding the

occupational therapists consent and demographic data is dealt with in Section 3.6.7 and the occupational therapists focus group is discussed and described in Section 3.6.8.

As the data was submitted the researcher monitored the data for completeness on a weekly basis and contacted the appropriate occupational therapists, occupational therapy specialists and research assistants regarding any missing data.

3.6.1 Written consent and demographic data

The data collection for gathering socio-demographic data and gaining written consent from participants is outlined in the enrolment process diagram (see Illustration 3.1); using the *Registration form* (Appendix 13, p.397)

Attempts were made to minimise participant burden, the research assistants met potential participants where it was most convenient for the participants to meet; either in their own home or at the community mental health team base and the additional outcome measures and data collection was kept to a minimum.

3.6.2 Baseline and post-intervention outcome measures

The primary (see Section 3.4.4.2.1) and secondary outcome measures (see Section 3.4.4.2.2) were completed with participants prior to commencing occupational therapy, by the research assistants (see Illustration 3.1). The research assistants were independent of the occupational therapists and the researcher to minimise bias. The outcome measurement was repeated with participants post-intervention or after six months of occupational therapy, by the

research assistants. All outcome measures completed by the research assistants were also timed for how long they took to administer.

Participants completed the COPM (see Section 3.4.4.2.5) when they commenced occupational therapy, repeating it prior to discharge or after six months of occupational therapy with the occupational therapist and this was recorded on the *Occupational therapy intervention log* (Appendix 13, p.399).

Completing the study outcome measures was anticipated to be a nonmaleficent conversation; however if any participants became upset or distressed in the process, they would be given the appropriate support by the research assistants. The research assistants were trained in how to respond in such circumstances and given the appropriate supervision and support should this situation occur.

3.6.3 Occupational therapy interventions

After each face to face contact with the participant, the occupational therapist recorded the intervention on the *Occupational therapy intervention log* (Appendix 13, p.399). These were coded using participant identification numbers and then sent to the researcher and research administrator.

3.6.4 Occupational therapy monitoring/ support of fidelity

Fidelity was assessed and monitored throughout the study to ensure that fidelity remained high throughout (West and Spring 2014). The occupational therapy clinical specialist in each centre reviewed and compared the *Occupational therapy intervention log* with what was recorded in the participant's case-notes, using the *Occupational therapy fidelity checklist* (see Appendix 13, p.405). This was carried out on a monthly basis with a random selection of two participants

(approximately 25 percent) from each occupational therapists caseload every month. This data was recorded and the checklists were discussed during professional supervision to support fidelity and any concerns were discussed with the researcher. At the end of the study's therapy intervention period, the occupational therapists recorded their views about the effectiveness of the occupational therapy for the individual participant on the *POINTER study occupational therapy intervention log.*

3.6.5 Questions/ queries and resolution log

The researcher and the occupational therapy clinical specialists maintained a *POINTER study log of questions/ queries and resolutions* (see Appendix 13, p.398) from conversations with each other and the occupational therapists. Information recorded was coded showing the centre number and the log was circulated to all those in the research study team, on a weekly basis to support fidelity.

3.6.6 POINTER study participant questionnaire

The POINTER study participant questionnaire (see Appendix 15), was carried out with the participants by the research assistants, after they had been discharged or after six months of the occupational therapy. It was not anticipated that the conversations would be sensitive, embarrassing or upsetting. If any participants became upset or distressed in the process, they would be given the appropriate support by the research assistants. The research assistants were trained in how to respond in such circumstances and given the appropriate supervision and support should this situation occur.

3.6.7 Occupational therapists consent and demographic info

Data collected from and about the occupational therapists and their experiences was socio-demographic data on the *POINTER study occupational therapist registration form* (Appendix 13, p.397). The occupational therapists consented separately for being an occupational therapist in the study (see Appendix 13, p.395) and for taking part in the occupational therapist focus group (see Appendix 13 p.396); this was discussed in Section 3.4.2.1.4.

3.6.8 Occupational therapists focus group

At the end of the study, an occupational therapist focus group was planned to be carried out in both centres with all the occupational therapists from that centre. The occupational therapy focus group was a group conversation was facilitated by the researcher using the *Occupational therapists focus group conversation guide* (see Appendix 15) about the occupational therapy provided and the use of the POINTER Study Protocol. It was anticipated that the topics would be nonmaleficent. Both focus groups were recorded and transcribed.

3.7 Data security of confidential personal data

Confidential participant information was coded using a participant identification numbering system, to ensure that the identities of the participants' were kept anonymous. Each occupational therapist was also given an identification number. Data collected from and about the occupational therapists and their experiences was socio-demographic data and the recording and transcripts of the focus group; this data was anonymised. Direct quotes from the participants and the occupational therapists were planned to be published; however these were anonymised so that individuals would not be identifiable.

3.7.1 Access to participants' personal data during the study?

The researcher, the research supervisors, occupational therapists, occupational therapy clinical specialists, the research assistants and research administrator had access to data about the participants. It was made explicit in the *POINTER participant consent form* (see Appendix 13, p.385) that members of the research team and the NHS Trust may look at their medical notes and data collected in the study where it was relevant to them taking part in the study. It was also made explicit in the *POINTER study occupational therapist information sheet* (see Appendix 13, p.391) that demographic data collected, would be confidential and that their identity would be anonymised.

3.7.2 Data storage

All written confidential data collected was sent via NHS emails with password protection to the POINTER study research administrator and stored on a master file with password protection. All written data was stored securely on the NHS computer system. The audio tapes from the focus groups were stored securely on an NHS premises, transcribed by the research administer; the audio tape recordings were wiped after transcription. The transcriptions were also stored securely on the NHS computer system. Data analysis was carried out on an NHS computer system; this analysis was coded data only.

Personal data was kept for three months after the study. Once the study was completed the primary data was stored securely at the University archives for secure storage for 10 years.

3.8 Data analysis

The data analysis of feasibility studies is not designed to detect treatment effect (Lancaster et al 2002). The analysis was focused on exploring and testing key uncertainties for a future pragmatic RCT of the effectiveness of occupational therapy at improving the participation in activities of everyday life with people with a diagnosis of psychosis, living in the community.

> The outcomes of most feasibility studies should be measured with descriptive statistics, qualitative analysis, and the compilation of basic data related to administrative and physical infrastructure (Tickle-Degnen 2013, p.172).

The data analysis utilized a combination of quantitative and qualitative approaches as this is consistent with the pragmatic theoretical perspective. This triangulation of methods minimises research bias and enhances the validity of the result by testing the consistency of findings obtained by different methods (Bowling, 2009).

3.8.1 Descriptive statistics

Means, standard deviations, frequencies and percentages were used to describe the outcomes, background demographic, social and clinical characteristics and baseline variables. These were also used as part of reporting about what the occupational therapy provided was, using the *TIDieR checklist* (Hoffmann et al 2014).

3.8.2 Analysis of indication of the effectiveness of the intervention

The TREND Checklist (Jarlais et al 2004) and *CONSORT 2010* (Moher et al 2010) recommend presenting a summary of the results for each study condition and the estimated effect size and its precision. A descriptive analysis of changes with a calculation of the effect size was planned of the pre- and post-

intervention scores. Firstly the normality of the outcome measure scores were to be tested using a kologomorov-smirnov test/ shaper-wilks test. If the data was normally distributed then the outcome measures were to be assessed using a paired t-test. If the data was not normally distributed, then a Wilcoxon signed rank test was to be used.

3.8.3 Analysis of process outcome data

Some statistical tests were considered to test the construct validity of the participation measures; as the participation measures didn't have strong reliability and validity testing. This would specifically test the concurrent criterion validity referring to the degree of convergence or divergence with a tried and tested indicator of the concept; which in this study was the Time Use Survey (Saks and Allsop 2007). This would be dependent of achieving the target sample size (see Section 3.5).

Content analysis was applied to the qualitative data generated from the occupational therapist focus groups; this was inductive as there was not enough former knowledge (Elo and Kyngas, 2008). This was triangulated with descriptive statistical data (as described in Section 3.8.1) from other sources to assess the process outcomes (see Section 3.4.4.3) of the study.

The results of the feasibility study are presented as the study outcomes in Chapter five and process outcomes in Chapter six. The development and evaluation of the occupational therapy intervention is presented in the next chapter (Chapter four).

Chapter 4 Occupational therapy intervention specification

‘Unravelling the Black Box’ (Sermeus 2015 p.112)

4.1 Introduction

Occupational therapy has been identified as a complex intervention (Creek 2003) and this definition fits the MRC (2008) criteria for complex interventions (see Section 1.6.4). There is a developing research methodology knowledge base about designing and evaluating complex interventions (see Section 1.7.1). Critically occupational therapy effectiveness research can now benefit from this developing knowledge base. The description of interventions in research trials has been identified as often unsatisfactory and poor (Hoffmann et al 2014). These findings echo the systematic review (see Section 2.5.2) conducted in this thesis of occupational therapy with individuals with a diagnosis of psychosis. It concluded that the quality of the intervention description was not always sufficient to enable replicability (see Section 2.6). There was also notably a wide variation in how occupational therapy was described and the outcomes expected as a result of therapy (see Section 2.5.9 and 2.5.3). This meant a fundamental aspect of this effectiveness study was to create a valid description of occupational therapy, embedding the intervention firmly in theory with related primary and secondary outcomes and in sufficient detail to be replicable. This process has been likened to *‘unravelling the black box’* (Sermeus 2015 p.112).

The methodology about how to design, develop and report on complex interventions is continuing to develop (Campbell et al 2000, Campbell et al 2007, Gitlin 2013, Johnston and Case-Smith 2009, Mohler et al 2012, MRC 2000, MRC 2008, Richards and Hallberg 2015). *Developing and evaluating*

complex interventions: new guidance (MRC 2008) acknowledges that the process of development through to the implementation of a complex intervention may take a wide range of forms. The need for comprehensive and transparent reporting of the development and evaluation of complex interventions has also been identified (MRC 2008, Mohler et al 2012). In response to this, the *Criteria for Reporting the Development and Evaluation of Complex Interventions in healthcare (CReDECI)* were developed by experts in the field, as a minimum standard to ensure high quality reporting in this area (Mohler et al 2012). Both sets of guidelines were therefore integral to the development and evaluation of this complex occupational therapy intervention and shaped the structure of this chapter.

The aim of this chapter was to articulate, in a transparent manner, the research approaches and processes considered and those utilised to develop the occupational therapy intervention specification for individuals with a diagnosis of psychosis, living in the community. The chapter starts by introducing the key elements of developing complex interventions (MRC 2008) and the guidance chosen to report comprehensively on the development of occupational therapy as a complex intervention for this study (Mohler et al 2012) (see Section 4.2). The approaches and processes to developing complex interventions are critiqued, identifying the core components, giving the rationale for the particular approach adopted in this study (see Section 4.3). The process utilised for developing the intervention specification is discussed (see Section 4.4) including; identifying the evidence base (see Section 4.4.1) and identifying/ developing theory (see Section 4.4.2). The steps taken to model the processes and outcomes of the intervention specification are then delineated in a sequential format, whilst acknowledging that some developmental aspects are

also iterative (see Section 4.4.3). The findings presented explicitly define the occupational therapy intervention (see Section 4.5), including its links to theory and outcomes (see Section 4.5.1). How it is intended to be operationalised (see Section 4.5.2) and delivered (see Section 4.5.3). To avoid duplication in the thesis, two parts of the findings integral to this chapter are presented in the Appendix: the Occupational therapy task analysis (Appendix 13, p.364) and Occupational therapy pathway (Appendix 13, p.365). This is due to them being a part of the POINTER study protocol (Appendix 13) and being oversized, as explained in the Methodology, chapter three. The validity and utility of this intervention specification was further evaluated through being utilised in the feasibility study (see Section 3.4.4.4).

4.2 Development and reporting of complex interventions

The MRC (2008) outline the development-evaluation-implementation process for complex interventions, which includes four main stages; development; feasibility/piloting; evaluation and implementation. Each stage is not completely 'stand-alone' and there are interactions between the phases that are not necessarily sequential (MRC 2008). The development of a complex intervention involves three key functions and activities (MRC 2008) (see Table 4.1). In this study these three key functions were utilized to structure the development of the intervention (see Section 4.4). The *CReDECI* was also utilised to support the transparent reporting of the development of the intervention specification (Mohler et al 2012). The six *CReDECI* are summarised in Table 4.1 and the table demonstrates how they can relate to the MRC (2008) guidance; the application of these in this study is delineated in Section 4.4.

4.2.1 Describing health intervention specifications for research

The importance of explicitly describing interventions and co-interventions is indicated by its place as part of the criteria for assessing the methodological quality of effectiveness studies (Steultjens et al 2002).

'Without a complete published description of interventions, clinicians and patients cannot reliably implement interventions that are shown to be useful, and other researchers cannot replicate or build on research findings' (Hoffmann et al 2014, p.1).

Development of complex interventions, key functions and activities, (MRC 2008, p.8).	**Development of complex interventions; criteria for reporting the development and evaluation of complex interventions in healthcare (CReDECI) (Mohler et al 2012, p.42)**
1. Identifying the evidence base	1. Description of the interventions underlying theoretical considerations
2. Identifying/ developing appropriate theory	
3. Modelling process and outcomes	2. Description of all components of the intervention 3. Rationale for the selection of the intervention's components 4. Illustration of any intended interactions between different components 5. Rationale for the aim/ essential functions of the intervention's components 6. Consideration of contextual factors and determinants of the setting in the modelling of the intervention

Table 4.1 Development and reporting of the development of complex interventions

The MRC (2008, p.5) states 'it is important to provide a detailed account of the intervention'; however it does not specify detailed expectations with regards to how to do this. Hoffmann et al (2014) recognised this and an international group of experts and stakeholders developed the *Template for Intervention Description and Replication (TIDieR) checklist and guide*. The 12 item checklist

is an extension of the intervention related aspects of the *CONSORT 2010 statement* (Schulz et al 2010) and the *SPIRIT statement* 2013 (Chan et al 2013). The *TIDieR checklist* items are outlined in brief in Box 4.1.

1.Brief name
2.Why
3.What (materials)
4.What (procedures)
5.Who provided
6.How
7.Where
8.When and how much
9.Tailoring
10.Modifications (made in the course of the research study)
11.How well (planned measurement adherence and fidelity)
12..How well (actual adherence and fidelity)

Box 4.1 *Template for Intervention Description and Replication (TIDieR) checklist* (Hoffmann et al 2014).

4.3 Approaches to developing complex interventions

There is no set method for developing complex interventions in effectiveness research (MRC 2008), as discussed in Section 4.1. Abraham et al (2015) acknowledges that there are a number of frameworks that offer guidance on how to manage the process of intervention mapping (IM) and briefly summarises the six planning stages involved in IM; these can be seen in Table 4.2. Sermeus (2015) critiqued different models for building complex interventions, identifying that this informs the general approach. Sermeus (2015) and Abraham et al (2015) subsequently proposed six stepped processes to modelling complex interventions and IM respectively; this is briefly outlined in Table 4.2. Both of these approaches were scrutinised in relation to the key steps for the development and reporting of the development of complex interventions as outlined in Table 4.1. The outcome of the appraisal identified

that each approach encompassed MRC (2008) key functions and activities of developing complex interventions. These two approaches sum up the considerations and decisions taken in how to develop the occupational therapy intervention specification for this study. An outline of the specific approach utilized for this study is also briefly given in Table 4.2. Whilst comparing the approaches to developing complex interventions, three main components emerge (see Table 4.2):

- Developing and describing the processes and outcomes of the complex intervention.
- Implementation considerations of the complex intervention.
- Evaluation of the processes and outcomes of the complex intervention.

Components of complex intervention development	Six stages of Intervention Mapping, (Abraham et al 2015)	Six-step modelling for complex interventions (Sermeus 2015)	Approaches to developing the occupational therapy intervention specification in this study
Developing and describing processes and outcomes	1. Needs assessment (e.g. What is the health problem?) 2. Objective setting (primary and secondary outcome objectives)	1. Installing a project team and formulating key objectives of the complex intervention	1. Engaging with the Researching Occupation Participation Effectiveness (ROPE) Group and use of expert opinion. 2. Doing a task analysis of the intervention; theory base, therapy goals, therapy objectives, key activities and therapy outcomes (Gitlin 2013).
	3. Identification of change mechanisms and techniques (processes and techniques which are active ingredients of the intervention)	2. Getting consensus on the components of the complex intervention 3. Clustering of clinical activities into key interventions and building a process flow	
Implementation considerations	4. Delivery methods (How best to deliver intervention?) 5. Implementation (How will the intervention be delivered in practice?)	4. Get the process organised and allocate resources 5. Detailed description of the key interventions	3. Applying the *Template for Intervention Description and Replication (TIDieR) checklist* (Hoffmann et al 2014).
Evaluation of the processes and outcomes	6. Evaluation (outcome and processes)	6. Translation into a set of process and outcome indicators.	4. Evaluating the outcomes and processes of the intervention (see Section 3.4.4)

Table 4.2 Approaches to developing complex interventions

4.3.1 Developing and describing complex intervention processes and outcomes

Developing and describing the processes and outcomes of the complex intervention are advocated as a key element in the developmental stage (MRC 2008). Establishing a project team is important when framing the key objectives of the complex intervention (Sermeus 2015). Abraham et al (2015) agree on setting the objectives early in the process. This study utilised a steering group, which was the Researching Occupation and Participation Effectiveness (ROPE) Steering Group. This was a collaboration of people from across England interested in fostering the development of effectiveness studies related to occupation and mental health. The ROPE Steering Group had a wealth of experience in research, service user involvement work and occupational therapy. It contributed to establishing and developing the parameters of the study and peer reviewed its progress. The details about what this involved, including the wider engagement and consultation with expert opinion is discussed in more depth in Section 4.4.3 (Step 4).

An important part of the process is to identify the active ingredients of the intervention (Abraham et al 2015) and gain consensus about the components of it (Sermeus 2015). These aspects are advocated as critical to identifying the processes and outcomes; however specific tools which facilitate this are not stipulated in detail. A task analysis had been used successfully for the development of a complex intervention for people with a diagnosis of depression (Gitlin et al 2012). It was used to facilitate the description of the intervention including making the links between theory and outcomes, both of which were identified as issues in the description of interventions in the Table

2.9. This task analysis was identified as an appropriate tool to enable the intervention to be explicitly revealed (see Section 4.4.3.1 for the application of the task analysis).

4.3.2 Implementing complex intervention

Implementation considerations of the complex intervention are driven by an appreciation of the growing body of knowledge that is implementation science (introduced Section 1.7.2). How the final intervention can achieve widespread adoption if proven effective is advocated to be addressed in the development stage taking the setting and likely chance of it being embedded into practice into consideration (Richards 2015). It is suggested that the scale of the implementation issue can be determined by understanding the gap between the intervention being developed/ tested and the way people are practising (Skolarus and Sales 2015). The scenario for this study is that the intervention being described for evaluation and potential implementation is actually already in practice in an NHS Trust in the North West of England. Therefore in this instance the knowledge and processes used in current practice can be drawn on to most accurately describe how the process will be organised and resources allocated (Sermeus 2015). Having the full and comprehensive details of the planned and actual delivery of the intervention was highlighted as a major issue in the systematic review (see Section 2.6). The *TIDieR checklist* (Hoffmann et al 2014) was applied to critique the descriptions of occupational therapy in the systematic review (see Table 2.9), to maintain consistency this was also used to structure the information about how the occupational therapy intervention would be delivered (see Section 4.5.3).

4.3.3 Evaluation of the processes and outcomes of the complex intervention

The evaluation of the processes and outcomes are featured in both approaches to developing complex interventions that were critiqued (Abraham et al 2015, Sermeus 2015), see Table 4.2.

'An outcome evaluation tests whether the intervention succeeded in changing its specified outcomes' (Abraham et al 2015, p.106).

Whereas:

'A process evaluation is designed to understand the mechanisms by which the intervention exerts its effects, getting into the 'black box' of the intervention' (Richards 2015, p.12).

The occupational therapy intervention outcomes (see Sections 3.4.4.1 and 3.4.4.2) and processes (see Sections 3.4.4.3 and 3.4.4.4) were evaluated as part of the feasibility study.

4.4 Developing the intervention specification

The intervention specification was developed within the developing and reporting of complex intervention frameworks discussed in Section 4.2 and is presented in the following sections using the three key functions and activities of developing complex interventions, outlined by the MRC (2008) as:

- 4.4.1 Identifying the evidence base
- 4.4.2 Identifying/ developing appropriate theory
- 4.4.3 Modelling process and outcomes

Embedded within Sections 4.4.1 to 4.4.3 is the application of the learning from critiquing the approaches to developing complex interventions that was discussed in Section 4.3. Including the explication of the approach taken to develop the occupational therapy intervention specification, briefly outlined in

Table 4.2. It is important to note that although the process is presented largely as linear to provide a narrative that makes sense, it was in fact iterative.

4.4.1 Identifying the evidence base

'You should begin by identifying the relevant existing evidence base, ideally by carrying out a systematic review' (MRC 2008 p.9).

This was achieved through the systematic review outlined in Chapter two. The review question asked: Does occupational therapy improve participation in activities of everyday life for adults with a diagnosis of psychosis? Four categories of occupational therapy interventions emerged; life skills; individual client-centred; activity-based groups and cognitive occupational therapy interventions (see Section 2.4.3). It was identified that the individual client-centred occupational therapy intervention category was the most appropriate grouping to inform an intervention specification for this study. There was a limited amount of effectiveness studies in this area; that is two RCTs, one CCT and two ODs (see Section 2.4.3). Furthermore following the quality assessment only the study carried out by Cook et al (2009) met the criteria for a high quality effectiveness study in this category (see Section 2.4.2). The primary outcome set out in the systematic review protocol was only partially reported on by both of the RCTs for individualised, client-centred occupational therapy interventions (Cook et al 2009, Edgelow and Krupa 2011) (see Section 2.4.5.1). There was no evidence of effectiveness from either RCT on the primary outcome and neither study measured the secondary outcome regarding quality of life or health related quality of life, therefore no evidence of effectiveness was found. Having no evidence of effect, does not mean an intervention is ineffective (Bullock and Bannigan 2011). In order to be able to draw valid and reliable conclusions about the effectiveness of individualised client-centred occupational

therapy interventions, more high quality RCTs are needed that measure the impact on participation in activities of everyday life.

It is acknowledged that the ideas for complex interventions can emerge from various sources which include practice and practitioners (MRC 2008). In this study practice driven evidence came from the collation of routine occupational therapy standardised outcome measure data in practice. The Canadian Occupational Performance Measure (COPM) was completed before and after individualised client-centred occupational therapy interventions in community mental health services across Lancashire, England (see Section 1.6.3). The data indicated a positive effect; service users with a diagnosis of psychosis were regularly achieving clinically significant change scores from the use of the COPM. This data was a key driver in prompting and developing this feasibility study; because I needed to find out if similar scores would be achieved with rigorous testing under research effectiveness conditions.

4.4.2 Identifying/ developing appropriate theory

The appropriate theory needs to be identified and/ or developed that underpins the intervention whether it is a new and developing intervention or an evaluation of an existing intervention (MRC 2008).

'A theory is a system of assumptions and principles devised to analyse, predict or explain phenomena' (Creek 2003 p.35).

The theories stated as underpinning each of the individualised client-centred effectiveness studies were extrapolated in the systematic review, Chapter two and are summarised in Table 4.3. Some of the theories have been synthesized into occupational therapy models which Hagedorn (1992, p.12) has described as:

'…providing an explanation of human behaviour in terms of occupational performance, and as a guide to treatment which is unique to treatment'.

Table 4.3 shows that there was no overall consensus on the theory underpinning individualised client-centred occupational therapy interventions from the systematic review.

Theory stated as underpinning individualised client-centred, occupational therapy interventions	**Author/s**
Occupational science and client centred approach	Cook el al (2009)
Canadian Model of Occupational Performance and Engagement (CMOP-E) and Recovery. Action Over Inertia (AOI) occupation-based intervention to improve occupational balance and engagement with people with severe mental illness (SMI).	Edgelow and Krupa (2011)
Goal Management Training (GMT) applied to daily tasks.	Katz and Keren (2011)
Activity-specific routines can be taught	
Everyday Life Rehabilitation (ELR) is a model for integrated rehabilitation, based on Occupational Therapy Intervention Process Model (OTIPM, Fisher 2009)	Lindstrom et al (2012)
Model of functional deficits	Mairs and Bradshaw (2004)

Table 4.3 Theories stated as underpinning individualised client-centred occupational therapy interventions in effectiveness studies

The NHS site from which the outcome measure data was derived (see Section 4.4.1) enables occupational therapy practice to draw on a multitude of occupational therapy models recognising that, practice needs to be flexible enough to enable models of practice to be chosen in response to individual service users' occupational needs. Creek (2003) supports this view and asserts:

'…adhering to one model without critical thought and evaluation can lead to routine practice rather than reasoned and reflective practice' (p.35).

Thus when considering, identifying and developing the theory behind the intervention the aim was to articulate the appropriate theory underpinning the

intervention that would enable it to be foundational to a range of occupational therapy models of practice. Acknowledging that, whatever the setting for the occupational therapy intervention, the global primary goal is shared, that is 'to enable people to participate in activities of everyday life' (WFOT 2012, p.15). Subsequently the theory for this occupational therapy intervention drew on core occupational therapy theory at the 'heart' of the profession. The foundational beliefs of occupational therapy are based on the principles of occupation and participation, and the importance of these to the health and well-being of the individual and society (Baum 2003, Law 2002, Vessby and Kjellberg 2010, WFOT 2012). This association between participation and health is recognised internationally wider than occupational therapy. For example *The ICF* (WHO 2001) describes participation or 'involvement in a life situation' as one of the core components of health (WHO 2001, p.10). This occupational therapy theory translates into occupational therapy practice which aims to enable people to participate in the activities of everyday life (WFOT 2012). The challenge is to translate occupational therapy theory into testable practice, finding a scientific way to further test and build the epistemology of occupational therapy. This testing of occupational therapy hypotheses in research was identified as needed in Section 1.3.3 (Creek and Hughes 2008). When identifying/ developing the occupational therapy theory for this thesis, hypotheses were deduced that enabled the intervention specification to be the vehicle to test this theory within research conditions. The following two hypotheses were developed:

- **Hypothesis 1**: Occupational therapy is associated with enhanced participation with activities of everyday life for individuals with a diagnosis of psychosis, living in the community.

- **Hypothesis 2:** Enhanced participation with activities of daily life is positively associated with health-related quality of life for individuals with a diagnosis of psychosis, living in the community.

4.4.3 Modelling processes and outcomes

The research effectiveness evidence base for individualised client-centred occupational therapy interventions was discussed in Section 4.4.1 and the related theory in Section 4.4.2. In the context of these findings it was concluded that the processes and outcomes that required modelling were those of an occupational therapy intervention in practice; where there was a positive clinical indication of effect for people with a diagnosis of psychosis living in the community. Subsequently the modelling was not about inventing a new intervention. It was focussed on describing occupational therapy practice already in existence and capturing it in a manner that enabled its effectiveness to be tested under rigorous research conditions.

'One of the most critical decisions is to compose a complex intervention out of existing evidence' (Sermeus, 2015, p.113).

When modelling the processes and outcomes for the intervention, all five of the relevant (individualised, client-centred occupational therapy interventions) effectiveness studies listed in Table 4.3 from the systematic review, Chapter two, were considered for direct application in this study. These were the most valid intervention descriptions to draw from because they were specifically focussed on occupational therapy effectiveness with people with a diagnosis of psychosis. They were also individualised, client-centred and the settings were in the community, all of which matched the parameters of this study. The analysis of effect in the systematic review showed no statistical evidence of effectiveness (see Section 2.4.5). The CCT study was assessed as having

insufficient methodological quality (Katz and Keren 2011) as were the two OD studies (Lindstrom et al 2012, Mairs and Bradshaw 2004) (see Section 2.4.2) and these were excluded from the analysis of effect. However all of the studies did not report on all of the outcomes stipulated in the systematic review (see Section 2.4.5) and it was considered valid to critique the key processes and outcomes of these studies to learn from them for this intervention specification.

The measurement of fidelity and adherence to the intervention was not stated in four of the relevant studies; this was the major issue that prevented the direct application of their interventions processes and outcomes to this study (Edgelow and Krupa 2011, Katz and Keren 2011, Lindstrom et al 2012, Mairs and Bradshaw 2004). In the RCT study assessed as having high methodological quality, occupational therapy was provided for people with a diagnosis of psychosis in the community by senior occupational therapists based in community mental health teams in the United Kingdom (Cook et al 2009). In this study an occupational therapy intervention schedule was used, fidelity was monitored via clinical supervision and adherence to the intervention schedule was audited via participant's therapy notes. The setting of community mental health teams and the client group which was in the Cook et al (2009) study was very similar to the setting and client group of concern in this thesis. The full intervention schedule was developed by Cook and Birrell (2007) and requested from the first author (Cook). The intervention schedule (see Appendix 16) was then critiqued using the task analysis approach for its direct utility in this study.

4.4.3.1 Task analysis

A task analysis approach, as introduced in Section 4.3.1, was taken; providing a framework from which to consider and define the intervention for RCT purposes.

'…This analysis entails breaking down the intervention by detailing its theory base, treatment goals, objectives and specific activities, and hypothesized primary (proximal) and secondary (distal) outcomes to ensure alignment of elements' (Gitlin 2013, p.182).

There was no set method about how to carry out this analysis (Giltlin 2013). Therefore a pragmatic approach to carrying out the task analysis for this study was applied. This involved combining the developing complex intervention methodology, with the existing evidence from occupational therapy research and practice within the task analysis framework. This created five broad steps to the process, as follows:

- **Step 1.** Critiquing the utility of existing occupational therapy schedule
- **Step 2**. Identifying practice-based evidence
- **Step 3**. Drafting the intervention specification
- **Step 4.** Consultation with experts in the field
- **Step 5.** Implementation considerations

The process is presented as linear; however it was also iterative, for example following consultations with experts in the field, the intervention specification and implementation considerations were further developed. The process is discussed and delineated further in this section.

Step 1. Critiquing the utility of existing occupational therapy intervention schedule

The first step in the task analysis was to assess the utility of the intervention schedule developed by Cook and Birrell (2007). This intervention schedule was initially created using *'Occupational therapy defined as a complex intervention'* (Creek 2003), followed by minor modifications from related literature on occupational therapy and mental health. Consensus methods refined the intervention schedule into 82 components that detailed occupational therapy actions under 11 stages (Cook and Birrell 2007). Fundamental to the task analysis process is the alignment of all of its elements (theory base, treatment goals, objectives and specific activities, and hypothesized primary (proximal) and secondary (distal) outcomes); guidance that was published after the development of the intervention schedule (Cook and Birrell 2007). The critique of the intervention schedule regarding its utility for this study identified that it was not completely possible to use it in its entirety. Firstly because the theory identified and described as underpinning the intervention schedule and the associated hypotheses, differed from that identified as underpinning the intervention in this study (see Section 4.4.2). Additionally the 82 components were substantially greater in number than those demonstrated within the task analysis example (Gitlin 2013). Further analysis of the intervention schedule was then carried out; the generic components were separated from the occupational therapy specific components of the intervention schedule Cook and Birrell (2007). This highlighted that 52 of the components were occupational therapy specific components. Therefore, whilst a landmark of its time; for today's purposes its scope was too wide. It provided a useful basis from which

to work and had been originally founded on *Occupational therapy defined as a complex intervention* (Creek 2003).

Step 2. Identifying practice-based evidence

As mentioned in the Introductory chapter I was also an occupational therapy professional lead with access to practice guidelines and standard operating procedures. A range of practice guidelines that were operational at the researchers NHS Trust at the time of the study, were critiqued for suitability to inform and provide practice-based evidence for the intervention specification. The *Occupational need pathway* (See Appendix 17) was identified as suitable. The pathway gave a high level overview of the occupational therapy processes and standards of practice expected and delivered in the NHS Trust. This was the same NHS Trust which was achieving positive outcomes, with people with a diagnosis of psychosis using the COPM (see Section 1.6.3).

Step 3. Drafting the intervention specification

I drafted the intervention specification using the framework outlined by Gitlin (2013). The foundational work to identify the theory and working hypotheses (see Section 4.4.2) was transferred into the task analysis framework as the 'Theory base' and 'Occupational therapy outcomes' (see Appendix 13 p.364). The treatment goals were aligned in-between the theory base and outcomes, set within the task analysis and also drawn from *POSITION STATEMENT: Occupational therapy, 2010* (WFOT 2012).

The development of the objectives and key activities were created by considering the occupational therapy components from the intervention schedule by Cook and Birrell (2007) and the occupational therapy process

outlined in *Occupational Therapy Defined as a Complex Intervention* (Creek 2003). This was combined with the occupational need pathway (Appendix 17) and practice driven knowledge. A summary of the where the main sources of evidence were derived from, to create the occupational therapy intervention specification, are shown in Table 4.4.

Aspect of task analysis (Gitlin 2013)	**Main sources of evidence for the intervention specification**
Theory	*POSITION STATEMENT: Occupational therapy, 2010* (WFOT 2012)
Therapy goals	
Therapy objectives	Intervention specification from: *Defining an occupational therapy intervention for people with a diagnosis of psychosis* (Cook and Birrell 2007) (Appendix 16) Occupational therapy defined as a complex intervention (Creek 2003) *Occupational need pathway* (LCFT) (Appendix 17)
Key activities	
Therapy outcomes	*POSITION STATEMENT: Occupational therapy, 2010* (WFOT 2012)

Table 4.4 Main sources of evidence for the intervention specification

Step 4. Consultations with experts in the field

Involving stakeholders in identifying and evaluating intervention components, determining feasibility and acceptability can generate knowledge which advances a working intervention prototype (Gitlin 2013). This can be carried out in a range of forms, one example would be to have:

'…interviews with 'stakeholders', i.e. those targeted by the intervention, or involved in its development or delivery' (MRC 2008, p.9).

A series of consultations with experts in the field was carried out between June 2014 and September 2014.

Experts in the field included occupational therapists, service users and carers, and other mental health professionals are outlines in Table 4.4.1.

Expert stakeholders consultations regarding intervention specification	Summary of main findings
Occupational therapy professional leads forum and occupational therapists in practice, LCFT, 23/01/2014 & 27/08/14	23/01/2014 Discussed combining occupational need pathways in practice with research evidence base; feedback was that it would be a progressive piece of work. 27/08/2014 Intervention specification was evaluated as having face validity with regards to describing occupational therapy practice.
Medical Director, 30/05/2014 & 18/07/2014	30/05/2014 Recommendation to make the intervention specification less complex for RCT purposes. The 'real time' assessment and adjustment of treatment appeared unique to occupational therapy. 18/07/2014 More streamlined version of intervention specification gave greater clarity.
Staff and Students at research student seminar series, York St John University, 11/06/2014 (also attended by ROPE Group members)	The description and connection between occupational therapy theory, goals, practice and outcomes was reported to have face validity. The objective 'Formulate occupational needs' was recommended to be expanded to describe more of the key activities involved.
CRN: Mental Health Fast-R Service, NIHR, 13/08/2014	No specific comments or questions about the intervention specification.
Clinical psychologist, 13/09/14	The intervention specification appeared to have utility for a RCT. Question regarding how practically measure fidelity to it?
Table 4.41 Summary of expert stakeholder consultations and findings	

The consultations involved presenting the draft intervention specification to the individuals/ groups of people for their critique regarding its face validity. Face validity is:

'…a subjective assessment by the investigators about whether the indicator, on the face of it, is a reasonable one and the items appear to be measuring the variables they claim to measure' (Bowling 2005, p.11-12).

Following each consultation appropriate amendments were made to the intervention specification and the overall feedback was that the intervention had face validity. The outcome of this process is graphically illustrated in the Appendix 13 p.364 ; which shows the final task analysis of the occupational therapy intervention specification. Ultimately the content validity and utility of the intervention specification was planned to be tested in the feasibility study by practising occupational therapists (see Section 3.4.4.4).

Step 5 Implementation considerations

Subsequent to the task analysis being completed, which described the individualised client-centred occupational therapy intervention for research purposes (see Appendix 13, p.364), it was translated into the occupational therapy pathway (see Appendix 13, p.365) which would enable it to be carried out in practice. The *TIDieR checklist* (Hoffmann et al 2014) was also utilised to fully operationalise the intervention in practice, ensuring that the reporting of the intervention would meet all the required standards for full research effectiveness reporting (see Table 4.5). Items two to nine in Table 4.5 (2.Why, 3.What materials, 4.What procedures, 5.Who provided, 6.How, 7.Where, 8.When and how much, 9.Tailoring) were discussed and agreed through the consultations with experts in the field (as outlined in Section 4.4.3, Step 4).

4.5 Findings

The findings from the development work of the individualised client-centred occupational therapy intervention, for people with a diagnosis of psychosis living in the community had three aspects to it:

- Occupational therapy intervention, task analysis (see Section 4.5.1)
- Occupational therapy pathway (see Section 4.5.2)
- Delivery details of the occupational therapy intervention (see Section 4.5.3)

4.5.1 Occupational therapy intervention task analysis

The occupational therapy task analysis is presented in Appendix 13, p.364; permission was granted to adapt and reproduce the framework from Gitlin (2013). It first summarises the overarching theory base which is derived from WFOT (2010). Followed by the goals of occupational therapy; to enable people to improve their participation in the activities of everyday life that are most meaningful (that they want to, need to or are expected to) to them (WFOT 2010). The goals connect to the objectives of occupational therapy, as it was anticipated that carrying out these eight occupational therapy objectives would lead to the achievement of the goals. The objectives start with assessing occupational performance (objective one) and formulation of occupational need (objective two) and the last objective is discharge from occupational therapy (objective eight). Each one of the objectives has key activities that operationalise it, for example: Objective five, implement occupational therapy interventions, is made up of six key activities. These are the key activities that the occupational therapist would need to be carrying out with the individual to achieve that objective. In contrast, the majority of objectives (three, four, six, seven and eight) are all made up of two key activities. The hypothesized outcomes (see Section 4.4.2) are presented at the bottom of the flow diagram to represent them as potential outcomes as a consequence of occupational therapy. The primary outcome being identified as: participation in activities of everyday life. The secondary outcomes to this were recognised as being: Self-reported experience of occupational performance and satisfaction as-well as

health-related quality of life. These proposed outcomes link directly back to occupational therapy theory (see Section 4.4.2).

4.5.2 Occupational therapy intervention pathway

The occupational therapy pathway is presented in Appendix 13 (p.365), and translates the occupational therapy task analysis (Appendix 13, p.364) into the occupational therapy pathway for the intervention. It is represented as linear and this is to reflect the general direction of objectives and key activities carried out with individuals. However the occupational therapy intervention is also iterative. Occupational therapists were expected to carry out the objectives and key activities with participants in the study, whilst also having the flexibility to use each objective and key activity as many times as appropriate for the individual they were working with. This tailoring of the intervention was designed to enable it to meet individual needs, therefore variation from one individual to another about the frequency of the key activities utilised was planned for. Fidelity to occupational therapy was achieved when all the objectives had been carried out with the participant (see Table 4.5). The occupational therapy pathway also represents what would happen if the occupational therapist reviewed goals with the individual and they weren't completely achieved to a satisfactory level for that individual; there would be an expectation that new occupational need goals would need to be set.

4.5.3 Delivery details of the occupational therapy intervention

This section provides information about how the intervention was planned to be delivered in practice and is summarised in Table 4.5 using the *TIDieR checklist* (Hoffmann et al 2014). The column on the left corresponds to the *TIDier checklist* items (Hoffmann et al 2014) and the column on the right provides the

delivery details for providing the occupational therapy intervention in this study. Table 4.5 is to be considered in conjunction with the information in the occupational therapy task analysis (see Appendix 13, p.364) and the occupational therapy pathway (see Appendix 13, p.365).

***TIDieR checklist* items (Hoffmann et al 2014)**	**Delivery details of the occupational therapy intervention**
1. Brief name	The POINTER (Participation…through Occupational INTtervention Effectiveness Research) occupational therapy intervention
2. Why	The goal of the intervention is to enable people who have a diagnosis of psychosis, living in the community to improve their participation in the activities of everyday life that are most meaningful (that they want to, need to or are expected to) to them (WFOT 2010).
3. What (materials)	The occupational therapist will utilise a standardised occupational therapy outcome measure; the Canadian Occupational Performance Measure (COPM). The occupational therapist will use a range of daily activities meaningful to the service user within their own homes and community.
4. What (procedures)	The procedure that occupational therapists will follow is the occupational therapy pathway (see Appendix 13, p.365). The occupational therapy task analysis sets this in the context of theory and expected outcomes (see Appendix 13, p.364).
5. Who provided	Qualified occupational therapists registered with the Health Care Professions Council (HCPC) (HCPC 2016). Occupational therapists will have experience of working with people with a diagnosis of psychosis, living in the community.
6. How	The mode of delivery will be face to face and provided individually.
7. Where	Service users own homes and communities, including community mental health team bases.
8. When and how much?	Service users will be provided with occupational therapy responsive to what their occupational needs are. The average expectation is weekly - two-weekly for up to six months.
Table 4.5 Delivery details of the occupational therapy intervention	

9. Tailoring	The intervention will be individualised to meet each service user's unique occupational needs. All the objectives in the occupational therapy pathway must be carried out, by the time the service user has had six months of occupational therapy (or at six months to achieve fidelity to POINTER occupational therapy). However there may be variation in the frequency of the use of the key activities.
10. Modifications (made in the course of the research study)	*Only applicable for reporting post-intervention (see Section 5.2.3.8)*
11. How well? (planned measurement adherence and fidelity)	***Measurement of adherence*** *recorded by the occupational therapist after each session on a scale of 0-10 (total adherence rating calculated by dividing total score, by the number of sessions). Participants to rate their level of adherence at the end of therapy on a scale 0-10* ***Measurement of fidelity*** *calculated from the occupational therapists details about what was provided in each of their sessions (total details from the start to the completion of therapy) compared to the objectives and key activities in the occupational therapy pathway, resulting in a percentage rating of fidelity*
12. How well?	*Actual adherence and fidelity to the intervention – only applicable for reporting post-intervention (see Section 5.2.3.10)*

Table 4.5 Delivery details of the occupational therapy intervention (continued)

Items one (see Section 3.4), five (see Section 3.4.2.1) and seven (see Section 3.4.1.3) were discussed in the methodology chapter three and are provided here to fully populate the *TIDieR checklist* items in to one place (Hoffman et al 2014). The second item (why) is generated directly from the goals on the task analysis (see Appendix 13, p364). Item three outlines that the planned materials that the occupational therapists would use, these were the Canadian Occupational Performance Measure (COPM) (see Section 3.4.4.2.5) and a range of daily activities meaningful to the service users within their own home and community (as demonstrated on the task analysis in Appendix 13, p.364) The planned procedures (item four), that the occupational therapists would

follow was the occupational therapy pathway (see Appendix 13, p.365) and connected to the occupational therapy task analysis (Appendix 13, p.364). The intervention was planned to be provided face to face on an individual basis (see item six). Items eight (when and how much) and nine (tailoring) both relate to the intervention being individualised and tailored to the specific need of the person the occupational therapists is working with. The intervention could be tailored within the parameters set; that all the occupational therapy objectives must have been carried out with the participant and that there could be variation in frequency and use of key activities. The information about the planned method of measuring adherence to occupational therapy and fidelity to it, are summarised in item eleven; the full details of this are given in the sections indicated, which are located in the Methodology, Chapter three. Two of the *TIDieR checklist* items (ten and twelve) are only applicable for reporting post-intervention and are reported in the Findings Chapter five.

4.6 Discussion

4.6.1 Developing, evaluating and testing the occupational therapy intervention

There are three key functions and activities to be fulfilled in the stage of developing complex interventions; however there is no set method for developing, evaluating and testing complex interventions for applied health research (MCR 2008). For example, the approach chosen for this study as discussed and outlined in Section 4.4, differed from that used by Cook and Birrell (2007). They developed an intervention schedule using a Delphi method to gain consensus on the interventions components used by occupational therapists with people with a diagnosis of psychosis; before using it in a pilot

randomised controlled trial (Cook and Birrell 2007). In contrast the method outlined and discussed in this study achieved face validity with experts in the field through a series of consultations (see Section 4.4.3, Step 4), with further testing of its validity and utility being through process measures set within the feasibility study (see Section 3.4.4.4). As process evaluations are recommended as often being highly valuable: providing insights into why an intervention fails unexpectedly; has unanticipated consequences or why a successful intervention works and how it can be optimised (MRC 2008).

4.6.2 The utility of the intervention specification for effectiveness research

The systematic review (see Section 2.6) identified that occupational therapy interventions need to be reported in sufficient detail to enable them to be replicated, ideally using the *TiDieR checklist* (Hoffmann et al 2014). Subsequently the *TIDier checklist* items (Hoffmann et al 2014) were utilised to support a thorough and rigorous description of the individualised, client-centred occupational therapy intervention (see Table 4.5). This framework was also carried through into the reporting of the results of the feasibility study (see Section 5.2.3).

Lessons learnt from the utility of Cook and Birrells (2007) Intervention schedule in the pilot study by Cook et al (2009) were also built on, as MRC (2008) assert the importance of basing the development of complex interventions on existing evidence. One of the major challenges was the contamination between the groups, with evidence showing that some of the participants in the treatment as usual received occupational therapy (Cook et al 2009). As other professionals may sometimes discuss occupation or do activities with people, this occupational therapy intervention specification stipulated that occupational therapy was only provided when all eight objectives (see Appendix 13, p.364)

were completed. These requirements around measuring fidelity to occupational therapy aimed to differentiate between the use of occupational therapy as a complex intervention, and the use of activities and occupations from other professionals and para-professionals within their practice.

It has been identified that:

'…occupational therapy was associated with some positive results concerning clinically significant improvement, beyond the average scores for this client group' (Cook et al 2009, p.49-50).

However this study did not expose detailed analysis about what the active ingredients were that brought about the change (Cook et al 2009). Process outcomes and measures were included in this feasibility study to aim to find out more about the potentially active ingredients (see Section 3.4.4.3 and 3.4.4.4). Also critical to this study was the use of a task analysis approach (Gitlin 2013) to describe the occupational therapy intervention; aiming to make a 'thread' from foundational occupational therapy theory, through the intervention to be provided and connected to the expected outcomes. The ultimate aim being to enable the epistemology of occupational therapy to be tested in applied clinical research, which was identified as an issue in the, Introductory chapter (see Section 1.3.3).

4.7 Conclusion

The occupational therapy intervention specification outlined in the task analysis (see Appendix 13, p.364) was developed based on the best available evidence from research and practice, within national and international guidelines for developing, evaluating and reporting on the development of complex interventions. The approach to achieving this has been based on the unique needs for developing this particular occupational therapy intervention

specification. The validity and utility of this intervention specification was further evaluated through being utilised in the feasibility study, which had process measures incorporated.

Chapter 5 Feasibility study results: study outcomes

5.1 Introduction

This was a feasibility study which aimed to explore how possible it would be to carry out a pragmatic RCT of occupational therapy with people with a diagnosis of psychosis, living in the community. Subsequently the aims and objectives (see Section 3.1.5) included both study outcomes and process outcomes; the challenge in presenting the results was that both are connected and distinct. Therefore the results are presented in two chapters; this Chapter (study outcomes) and Chapter six (process outcomes), with the discussion of the results for each of the objectives of the study being synthesized in Chapter seven.

This chapter presents the study outcome results of the feasibility study, together with the details about what occupational therapy intervention was provided (Section 5.2.3). This includes the actual process of assessing fidelity and adherence (Section 5.2.3.9). The extent of the fidelity and adherence to the delivery of the intervention as planned is reported (see Section 5.2.3.10). Details about what other (non-occupational therapy) interventions were received by the participants in the study are given (see Section 5.2.4). The numbers used for the analysis are stated (see Section 5.2.5). The outcomes and estimation are presented (see Section 5.2.6), including the primary outcomes (see Section 5.2.6.1) and secondary outcomes (see Section 5.2.6.2). Then the findings regarding the occupational therapists rating of effectiveness are summarised (see Section 5.2.7). Confirmation of the approach to ancillary analysis is given (see Section 5.2.8) and the study's results with regards to no-harms (see Section 5.2.9).

This chapter presents the outcome results of the feasibility study in a manner that is consistent with frameworks and guidance introduced (see Section 2.4 and 3.4), that is:

- *CONSORT Statement 2010* (Moher et al 2010)
- *Transparent Reporting of Evaluations with Non-randomized Designs (TREND) statement* (Jarlais et al 2004)
- *Improving the reporting of pragmatic trials: an extension of the CONSORT statement for* (Zwarenstein et al 2008)
- *Template for intervention description and replication (TIDieR) checklist and guide* (Hoffmann et al 2014)

5.2 Results: study outcomes

5.2.1 Participant flow

The flow of participants through the study is summarised in Illustration 5.1. As recommended the participant flow diagram includes the following information related to the reporting of pragmatic trials:

Number of participants or units approached to take part in the trial, the number which were eligible, and reasons for non-participation should be reported (Zwarenstein et al 2008, p.30).

Of the 36 service users identified as potentially eligible, twenty participants were recruited into the study, which is approximately 56 percent of those initially identified.

Twenty participants commenced occupational therapy and four participants withdrew during therapy; occupational therapy was completed with 16 (80%) of the 20 participants recruited. Two participants were lost to follow up for the post-intervention outcome measures.

Recruitment commenced on the 01/01/2014 and continued for three months.

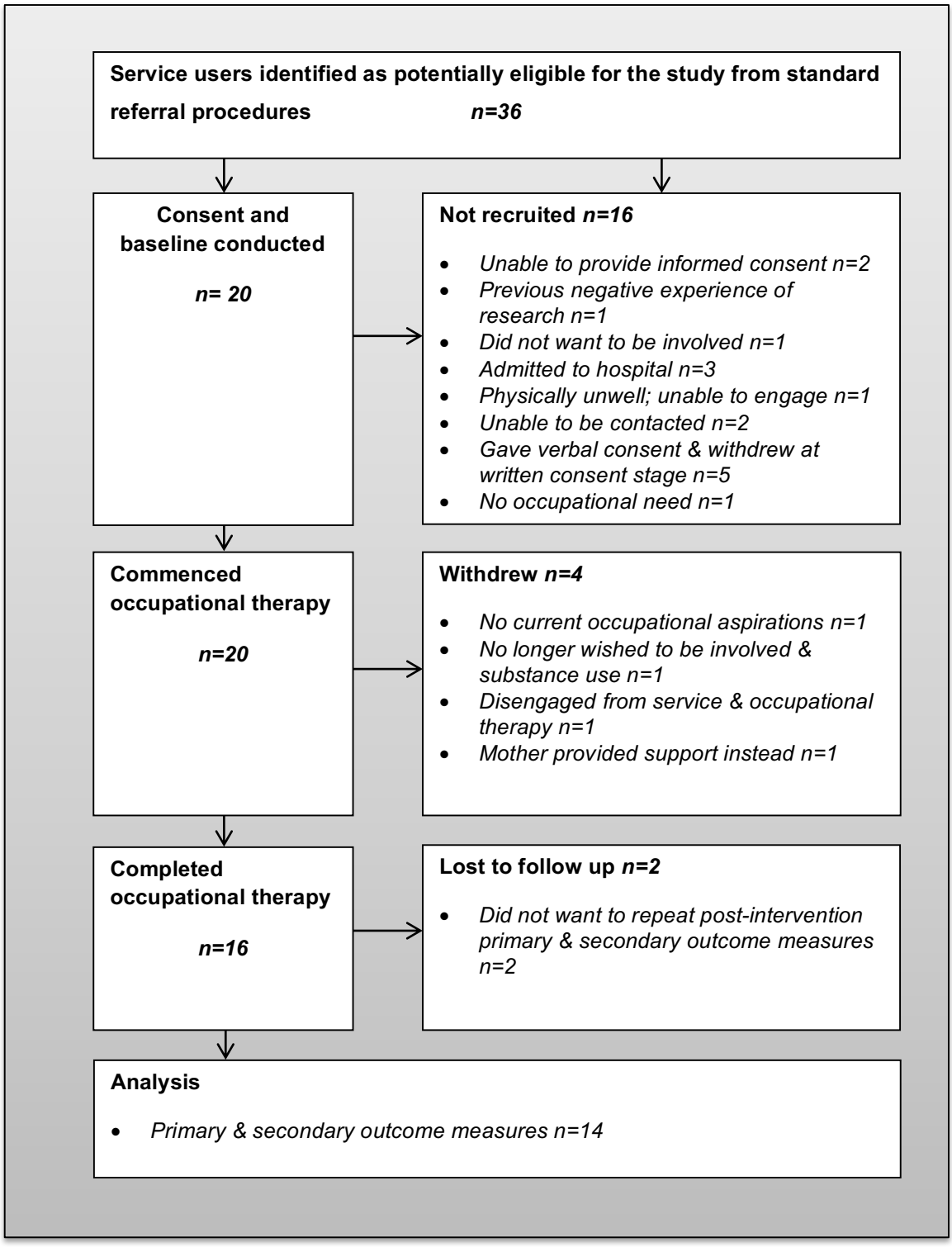

Illustration 5.1 Recruitment and participant flow through the study

5.2.2 Baseline Characteristics

Baseline demographic characteristics of participants are presented in Table 5.1

Demographic characteristics	Participants completed occupational therapy (n=16)	Participants with-drew from occupational therapy (n=4)	Total participants (n=20)
Gender: Male	12 (75 %)	3 (75%)	15 (75%)
Gender: Female	4 (25%)	1 (25%)	5 (25%)
Age (years): mean (SD)	43.06 (13.59)	46 (18.13)	43.65 (14.11)
Diagnosis (non-affective psychosis)	13 (81.2%)	1(25%)	14 (70%)
Diagnosis (affective psychosis)	3 (18.8%)	3 (75%)	6 (30%)
Length of time since diagnosis psychosis (years): mean (SD)	13.13 (12.69)	10.25 (17.17)	12.55 (13.23)

Table 5.1 Baseline demographic characteristics of participants

Due to the small sample size, statistical analysis was not appropriate. The descriptive statistics show that both of the groups of participants who completed and withdrew from therapy had the same ratio of male to female participants (75% to 25%). There were some similarities between those who completed therapy and those who withdrew, the mean age in years of the two groups was within three years and the mean length of time since diagnosis was also within three years. The biggest difference between the two groups was the diagnosis of their mental health problem. The majority of participants (n=13, 81.2%) who completed therapy had a diagnosis of non-affective psychosis, this diagnosis was in the minority for the participants (n=1, 25%) who withdrew from therapy.

The baseline social and clinical characteristics of participants who completed and withdrew from therapy are presented in Table 5.2.

Social and clinical characteristics	Participants completed occupational therapy (n=16)	Participants with-drew occupational therapy (n=4)	Total participants (n=20)
Employment status (employed)	1 (6.25%)	0	1 (5%)
Employment status (retired)	1 (6.25%)	1 (25%)	2 (10%)
Employment status (unemployed)	14 (87.5%)	3 (75%)	17 (85%)
HoNOS score (2) *(mild problem but definitely present with activities of daily living)*	12 (75%)	3 (75%)	15 (75%)
HoNOS score (3) *(moderately severe with activities of daily living)*	4 (25%)	1 (25%)	5 (25%)
Previous experience of occupational therapy (yes)	10 (62.5%)	2 (50%)	12 (60%)
Time use in constructive economic activity (hours per week): mean (SD)	6.94 (12.99)	6.2 (9.5)	6.79 (12.12)
Time use in structured activity (hours per week): mean (SD)	13.2 (14.36)	9.98 (8.71)	12.35 (13.3)
Notes: SD = standard deviation			

Table 5.2 Baseline social and clinical characteristics of participants

The data shows that only one participant from all those that were recruited was in employment and that the majority of participants were unemployed (n=17, 85%). The HoNOS scores for the two groups had the same ratio (75% to 25%) for scores of two or three. Sixty percent of all the participants had previously experienced occupational therapy; however for the participants who withdrew from therapy, this was lower than this at a mean at 50 percent. The baseline scores of the primary outcome measure of time use showed that the overall mean score for all those recruited was 6.79 (SD 12.12) hours per week in constructive economic activity, with the two group scores sitting either side of this. The participants who completed therapy reported a mean of 6.94 (SD 12.99) hours per week in constructive economic activity compared to those who withdrew from therapy, who had a mean score of 6.2 (SD 9.5) hours per week.

Time use in structured activity had an overall mean score of 12.35 (SD 13.3) hours per week for all of the participants recruited into the study. Again the mean for those who completed therapy 13.2 (SD 14.36) and those who withdrew 9.98 (SD 8.71) was positioned either side of this. Those who completed therapy spent on average 3.22 hours per week more doing structured activity than those participants who withdrew from therapy, at baseline. Therefore the two groups were not equal at baseline regarding the primary outcome measure scores, those who completed therapy started from a point of participating in more constructive economic and structured activity.

5.2.3 Intervention

The reporting guidelines for the intervention provided, advocate that details of the interventions intended for the study group and how and when they were actually delivered need to be reported (Jarlais et al 2004, Zwarenstein et al 2008). The procedure for the intervention is represented in the occupational therapy intervention pathway (Appendix 13 p.365), which is underpinned by the occupational therapy task analysis (Appendix 13 p.364). The delivery details of the intervention intended are provided in Table 4.5. The intervention actually delivered is reported in this chapter using the *TIDieR checklist* (Hoffmann et al 2014). The items reported from the *TIDieR checklist* and guidelines in this section are: what materials (3), what procedures (4), who provided (5), how (6), where (7), when and how much (8), tailoring (9), modifications (10) and how well planned (measurement of fidelity and adherence) (11), how well actual (extent to which the intervention was delivered as planned) (12). These items structure the presentation of the findings regarding the occupational therapy provided. The occupational therapy delivery data presented is provided for

those participants who completed occupational therapy and those whom withdrew, to be able to compare experiences.

5.2.3.1 What; materials used in the intervention *(Item 3, TIDieR checklist)*

The materials used to provide the intervention are reported in Table 5.3; the column on the left represents the planned delivery materials (see Table 4.5 for full planned delivery details) and the second and third columns provide information about the actual materials used for the delivery of occupational therapy in the study. The planned materials were used fully with 14 (87.5%) of the participants who completed therapy. These were not used with one participant who had one intervention contact only. The planned materials were only used with two participants (50%) of the four who withdrew.

What (materials) used	Participants who completed occupational therapy (n=16)	Participants who withdrew (n=4)
COPM	n=14	n=2
Range of daily activities meaningful to the service user within their own homes and community	n=15	n=2

Table 5.3 A summary of the materials used to provide the occupational therapy intervention in this study

5.2.3.2 What: procedures were used to deliver occupational therapy *(Item 4, TIDieR checklist)*

As described in Section 4.5.3 the procedure for the intervention was to use the occupational therapy pathway (see Appendix 13, p.365), in the context of the occupational therapy task analysis (see Appendix 13, p.364).Together with the

planned materials, to enable participants to participate in their activities of everyday life.

The bar chart in Illustration 5.2 shows the key activities from the occupational therapy pathway that were recorded by the occupational therapists, as being provided for participants who completed occupational therapy and/ or who received six months of occupational therapy; this totalled 188 contacts. The information for those participants who withdrew from occupational therapy is provided later in this section. Both bar charts present the occupational therapy key activities, each form part of the eight occupational therapy objectives (outlined in full in Appendix 13, p.364):

- Objective 1.Assess occupational performance (1a, 1b, 1c)
- Objective 2.Formulate occupational needs (2a, 2b, 2c, 2d)
- Objective 3.Set occupational therapy goals (3a, 3b)
- Objective 4.Plan occupational therapy interventions (4a, 4b)
- Objective 5.Implement occupational therapy interventions (5, 5a, 5b, 5c, 5d, 5e)
- Objective 6.Reassess occupational performance (6a, 6b)
- Objective 7.Review occupational need goals (7a, 7b)
- Objective 8.Discharge from occupational therapy (8a, 8b)

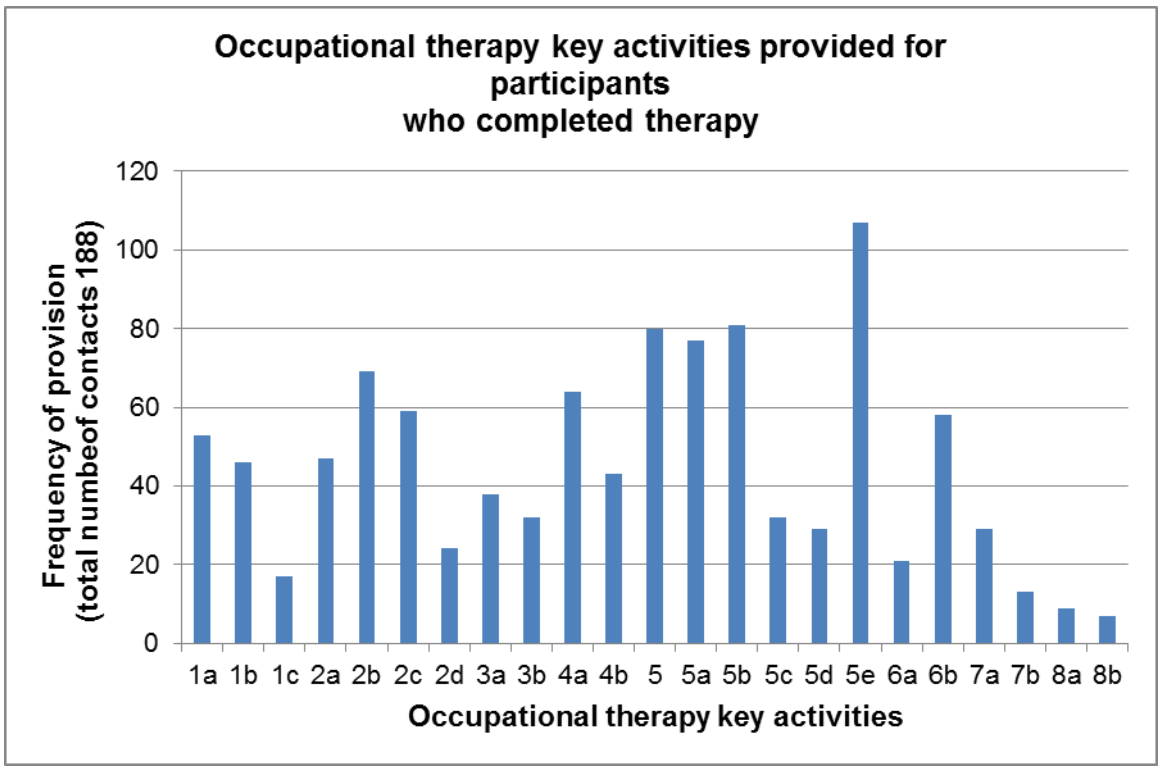

Illustration 5.2 Occupational therapy key activities provided for participants who completed therapy

The information presented in Illustration 5.2 demonstrates that all of the procedures outlined in the occupational therapy pathway were utilised by the occupational therapists within this study.

The key activity provided most frequently was 5e (Reflect and evaluate on-going progress in real time) within objective five which covers implement occupational therapy interventions, it was provided 107 (10.34%) times. The key activities carried out the least were within objective eight, 8a (Occupational needs have been met to a satisfactory level for the individual), which was provided on nine (0.87%) occasions and 8b (Individual is discharged from occupational therapy) was provided seven (0.67%) times.

Occupational therapy objective five: implementing occupational therapy interventions

This objective was made up of six key activities, as already reported: 5e. Reflecting and evaluating progress in real time was the most frequently provided key activity (provided 107 times, 10.34%). Three of the key activities in this objective were provided with similar frequency, they were: 5. Enable "make possible" for the individual to successfully participate in an activity/ occupation meaningful to them (provided 80 times, 7.73%); 5a. Use activities/ or occupations that have meaning for the individual (provided 77 times, 7.44%); 5b. Use activities/ or occupations to maintain/ increase the individuals skills & abilities (provided 81 times, 7.82%). The least frequently provided key activities were; 5c. Adapt/ use new activities & occupations with the individual (provided 32 times, 3.09%) and 5d. Adapt/ use new environments that activities & occupations occur in for the individual (provided 29 times, 2.8%).

Illustration 5.3 summarises the occupational therapy key activities provided for those participants who withdrew from occupational therapy: a total of 17 contacts. The information presented shows that for the participants who withdrew from occupational therapy, not all of the procedures outlined in the occupational therapy pathway were utilised with them. The majority of key activities were within the first two objectives; that is assessing occupational performance (provided 24 times, 29.63%) and formulating occupational needs provided 34 times, 41.98%).

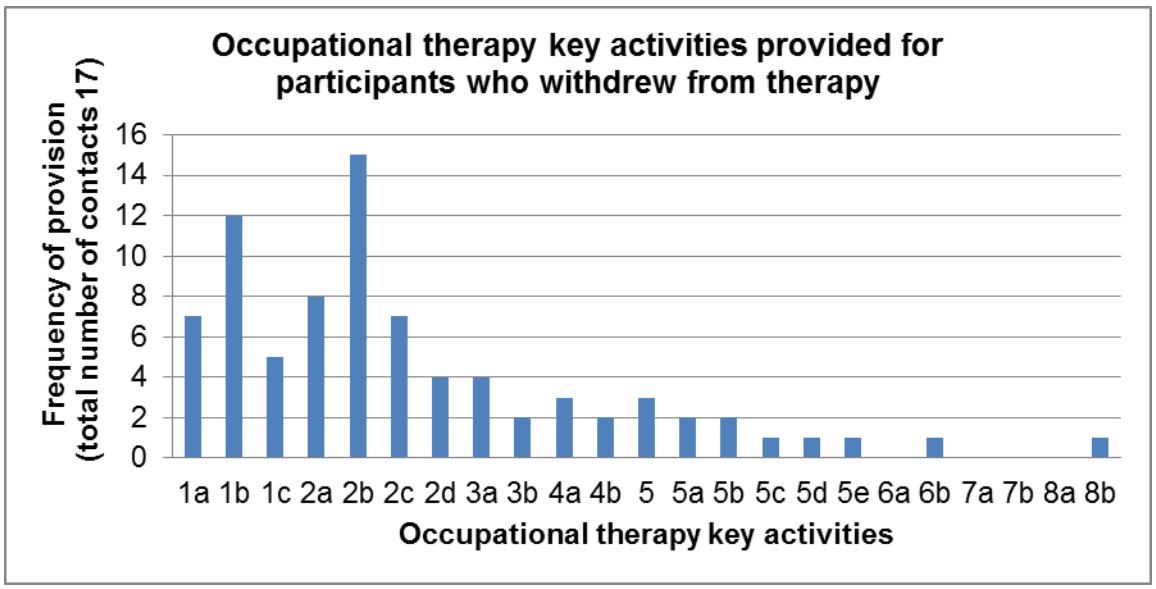

Illustration 5.3 Occupational therapy procedures provided for participants who withdrew from therapy

5.2.3.3 Who provided: occupational therapy intervention *(Item 5, TIDieR checklist)*

The occupational therapy intervention was provided by seven occupational therapists; three from Centre one and four from Centre two. All the occupational therapists were registered with the HCPC (HCPC 2016). The demographic information about the occupational therapists is summarised in Table 5.4. The majority (57%) were senior occupational therapists, mostly from Centre two and one consultant occupational therapist, 8b working from Centre one. Forty six years was the mean age of all the occupational therapists, with Centre two having the largest age range from 33 to 57 years. There was a nine year difference in the length of time since qualifying, with the occupational therapists in Centre two having a mean score of 19 years.

Characteristics	Occupational therapists		
	Centre one (n=3)	Centre two (n=4)	Total across both centres (n=7)
Gender: Male	3 (100%)	-	3 (43%)
Gender: Female	-	4 (100%)	4 (57%)
Agenda for change banding: 6	1 (33%)	3 (75%)	4 (57%)
Agenda for change banding: 7	1 (33%	1 (25%)	2 (29%)
Agenda for change banding: 8b	1 (33%)	-	1 (14%)
Age in years: mean (SD)	49.33 (1.53)	43 (11.58)	45.71 (8.9)
Length of time since qualifying in years: mean (SD)	18.67 (8.14)	10 (3.27)	13.71 (7)

Table 5.4 Demographic information for occupational therapists who provided occupational therapy in this study

There were differences between the team settings of the occupational therapists from Centre one and two. The occupational therapists worked in four different types of mental health teams shown in Table 5.5, all of these teams were based in the community and three of these (all from Centre one) specialised in working with people with a diagnosis of psychosis. Two occupational therapists were based in specialist community psychosis teams and one worked in early intervention for psychosis. Whilst the team setting for three of the occupational therapists from Centre two was community mental health teams settings and one occupational therapist was in a mental health recovery team.

	Occupational therapists Frequency (percentage)		
Team setting information	**Centre one (n=3)**	**Centre two (n=4)**	**Total (n=7)**
Community mental health team	0	3 (75%)	3 (43%)
Mental health recovery team	0	1 (25%)	1 (14%)
Early intervention in psychosis team	1 (33%)	0	1 (14%)
Community psychosis team	2 (67%)	0	2 (29%)

Table 5.5 Occupational therapist's team setting

The mean percentage from all of the occupational therapists (n=7) existing caseloads that provided occupational therapy interventions was 71 percent, with a broad range of 20-100 percent. Table 5.6 summarises these details and breaks them down for each centre who were positioned either side of this mean, with Centre one having the lowest at 47 percent and the mean of Centre two being 90 percent. The occupational therapists were trained in the use of the POINTER Study protocol (see Appendix 13) and the use of the COPM.

	Occupational therapists Mean (range)		
Occupational therapy caseload	**Centre one (n=3)**	**Centre two (n=4)**	**Total (n=7)**
Percentage of existing caseload; providing occupational therapy interventions	47% (20-90)	90% (78-100)	71% (20-100)

Table 5.6 Occupational therapist's occupational therapy caseloads

5.2.3.4 How: modes of delivery *(Item 6, TIDieR checklist)*

Based on the descriptions provided from the occupational therapists, the mode of delivery of all of the occupational therapy interventions were face to face and on a one to one basis between the occupational therapist and the participant.

5.2.3.5 Where: types of locations *(Item 7, TIDieR checklist)*

The occupational therapy interventions for those who completed therapy were mostly carried out in the participants own homes (frequency 144, 76.59%) or in the community (frequency 33, 17.55%). Telephone (frequency 2, 1.06%), CMHT (frequency 2, 1.06%), and participants own home and community (frequency 7, 3.72%).

The participants who withdrew from therapy had 15 (94%) of their occupational therapy contacts in their own homes and one (6%) was carried out in the community mental health team base.

5.2.3.6 When and how much *(Item 8, TIDieR checklist)*

The *TIDieR guidelines* recommend describing:

> …the number of times that the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose (Hoffmann et al 2014, p. 11).

The results are presented in Table 5.7 for participants who completed therapy and Table 5.8 for participants who withdrew from therapy. These provide information about the number of times occupational therapy was provided, over what time period, the intensity (length of time of the intervention) and the frequency (e.g. weekly).

The participants (n=16) who completed therapy received a mean amount of 11.75 (6.58SD) occupational therapy sessions. Illustration 5.4 gives a full breakdown of the length of all of these sessions, showing that one participant received only one session and that the highest number of sessions provided was 25.

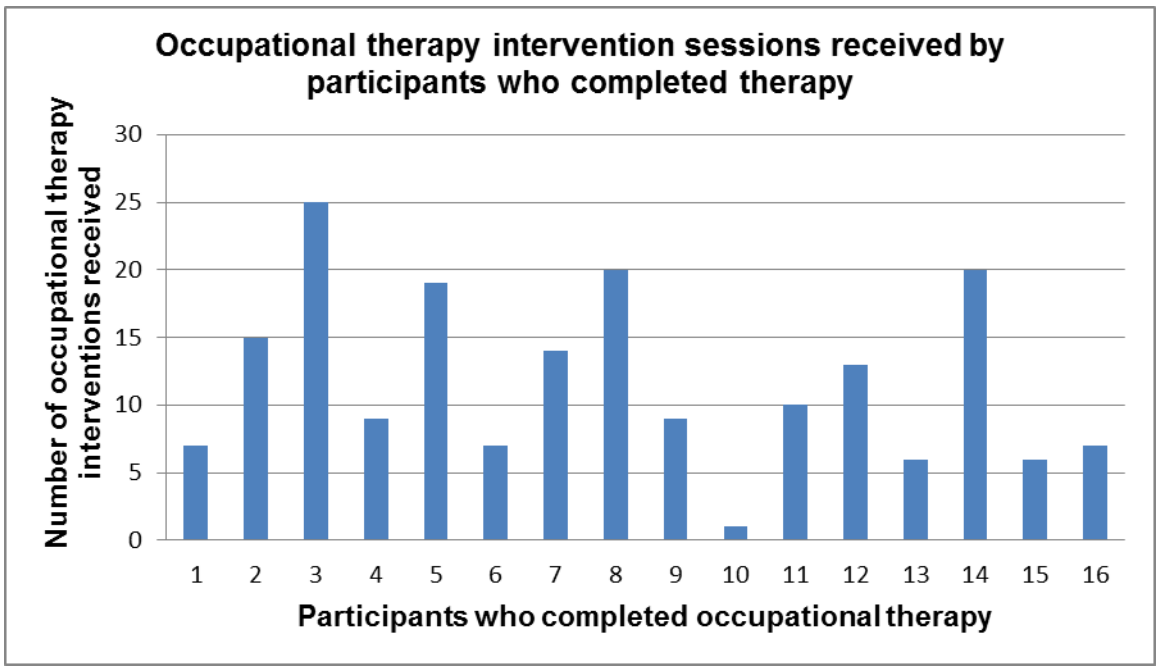

Illustration 5.4 Occupational therapy intervention sessions received by participants who completed therapy

A summary of the occupational therapy received by participants as reported by the occupational therapists is presented in Table 5.7.

Occupational therapy received by participants (n=16) who completed therapy	**Mean (SD, standard deviation)**
Number of occupational therapy intervention sessions	11.75 (6.58)
Duration (over what period of time in weeks)	19.06 (6.79)
Intensity (length of time of each intervention session in minutes)	65.15 (23.55)

Table 5.7 The amount of occupational therapy received by participants who completed therapy

The details about 'when and how much' occupational therapy the participants who withdrew received is summarised in Table 5.8.

Occupational therapy received by participants who withdrew from occupational therapy	**Mean (SD, standard deviation)**
Number of occupational therapy intervention sessions	4 (1.41)
Duration (over what period of time in weeks)	4.5 (2.87)
Intensity (length of time of each intervention in minutes)	51.86 (7.47)

Table 5.8 The amount of occupational therapy received by participants who withdrew from therapy

5.2.3.7 Tailoring: how the intervention was personalised *(Item 9, TIDieR checklist)*

The nature of the occupational therapy intervention was that it was tailored, which means it is individualised to meet each participants individual needs (see Table 4.5). The tailoring needed to be provided within the occupational therapy pathway framework to maintain the fidelity of the occupational therapy intervention; this is reported in Section 5.2.3.10).

'If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when and how' (Hoffmann et al 2014, p.11).

The details of the tailoring were reported in the following sections:

- What intervention was provided (Section 5.2.3.5)
- When the intervention was provided (Section 5.2.3.6)
- How the intervention was provided (Section 5.2.3.4)

5.2.3.8 Modifications: If the intervention was modified, describe changes *(Item 10, TIDieR checklist)*

Modifications refers, to if the intervention was modified during the course of the study and the *TIDieR checklist* recommends describing such changes (Hoffmann et al 2014).

Occupational therapy not captured using the occupational therapy pathway

The occupational therapists recorded the occasions when they provided other aspects of occupational therapy not already described in the occupational therapy pathway. This was described by occupational therapists four times and

on each occasion this was within the occupational therapy session (provided as per the occupational therapy pathway). This equated to two percent of the total (188) occupational therapy intervention sessions provided to those who completed therapy. No modifications were made to the sessions of those participants who withdrew from therapy. Box 5.1 lists the descriptions of the other aspects of occupational therapy provided and not described in the occupational therapy pathway. Three of the descriptions involved education about the individual's diagnosis and coping strategies related to meaningful occupation or functioning. The use of an activity diary was also described.

- Education re: anxiety to increase service users understanding of what's happening and support graded return to meaningful occupation
- Provide information and discuss the importance of meaningful activity in promoting and maintaining mental health and wellbeing. Reviewed activity diaries that service user had completed to highlight individualised impact of meaningful and non-meaningful activity
- Educational strategies regarding diagnosis, coping strategies and functioning
- Mental health condition education linked to meaningful occupation

Box 5.1 Descriptions of 'other' aspects of occupational therapy provided, not already described as part of the occupational therapy pathway

Non-occupational therapy input provided by the occupational therapists

Non-occupational therapy input was defined as interventions provided for the participants, which was not occupational therapy. The occupational therapists recorded providing 29 instances of non-occupational therapy interventions, on 21 occasions (12% of the total amount of occupational therapy intervention sessions provided). These were provided within the occupational therapy sessions. On eight occasions these were provided completely separately to the occupational therapy sessions; these were not counted within the 188

occupational therapy sessions. There were no instances recorded for those who withdrew from therapy. Illustration 5.5 shows the interventions that were described as non-occupational therapy by the occupational therapists.

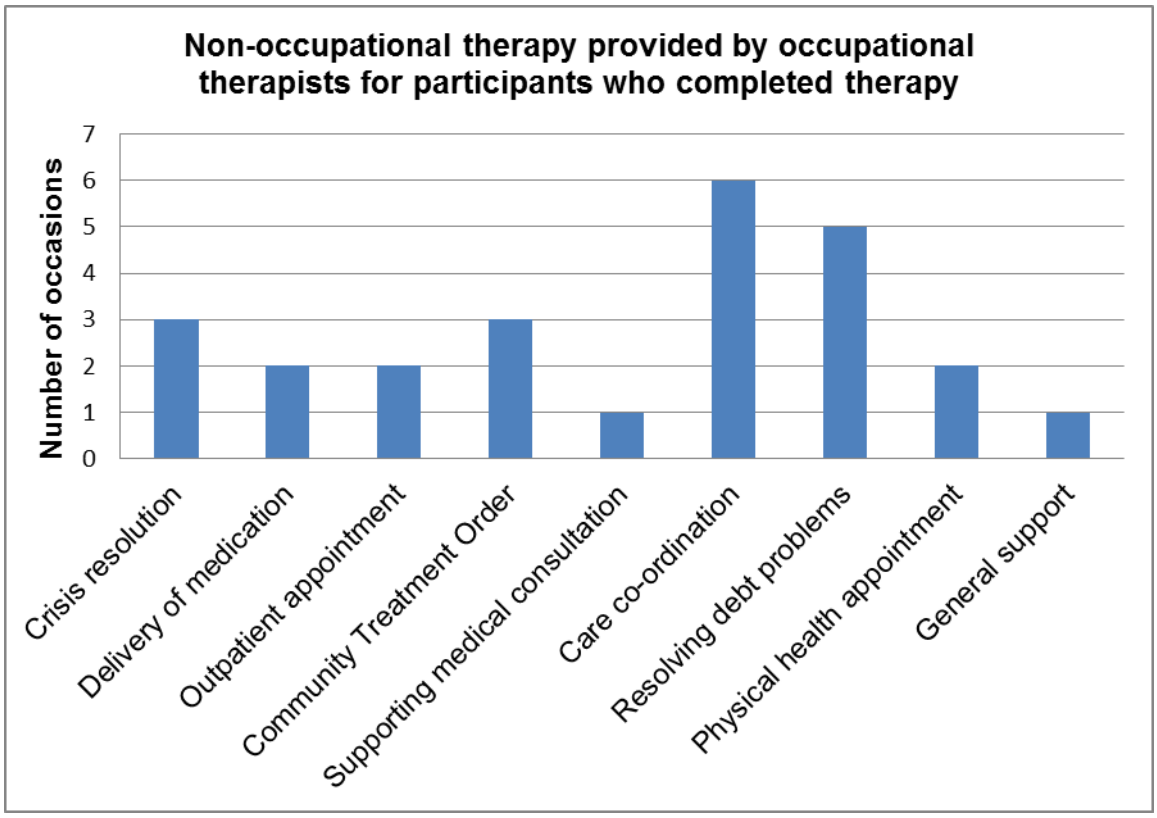

Illustration 5.5 Non-occupational therapy interventions provided by occupational therapists for those who completed therapy

5.2.3.9 How well (planned): How fidelity and adherence were actually assessed *(Item 11, TIDieR checklist)*

This section relates to how fidelity and adherence were actually assessed and it is also recommended to describe any strategies that were used to maintain or improve fidelity (Hoffmann et al 2014). The planned method for assessing fidelity and adherence were outlined in Table 4.5.

Actual procedure for assessing fidelity

The overall fidelity to the occupational therapy pathway was assessed as planned, using the occupational therapy log details to assess how much the eight objectives of the occupational therapy pathway were provided.

Actual strategies for maintaining or improving fidelity

- Fidelity was supported in both centres by monthly supervision of the occupational therapists from the occupational therapy clinical specialist (Centre two) and researcher (Centre one)

- A fidelity monitoring process
- In Centre two some informal peer to peer supervision occurred between the occupational therapists providing therapy for the study
- *Questions, queries and resolution log* was utilised (examples of this can be seen in Appendix 18). This was regularly circulated to all of the occupational therapists and research assistants involved.

Actual fidelity monitoring process

A dedicated occupational therapy clinical specialist from Centre two carried out the fidelity checks for Centre two. There was no occupational therapy clinical specialist from Centre one who was able to do the fidelity checks; therefore the researcher carried out this role. Fidelity to the intervention was monitored as planned. Any discrepancies were discussed during supervision with the occupational therapist; agreement was reached about actual recording on the log and updated if necessary. Fidelity monitoring assessments were planned to be carried out with a random sample of 25 percent of each occupational therapists caseload. These were actually carried out for 62% of the occupational therapy intervention sessions with the participants who completed

therapy. There was a difference of 44% between the total occupational therapists caseload monitored for fidelity between Centre one and two. Table 5.9 summarises the fidelity checks for the participants who completed therapy.

	Centre one	Centre two	Total
Number of occupational therapy intervention sessions provided	56	132	188
Number of fidelity checks carried out	52	65	117
Percentage of total caseload assessed	93%	49%	62%

Table 5.9 Fidelity checks carried out with participants who completed therapy

Table 5.10 shows the fidelity checks for the participants who withdrew from therapy.

	Centre one	Centre two	Total
Number of occupational therapy intervention sessions provided	7	9	16
Number of fidelity checks carried out	1	2	3
Percentage of total caseload assessed	14%	22%	19%

Table 5.10 Fidelity checks carried out with participants who withdrew from therapy.

Actual procedure for assessing adherence

Adherence was assessed as planned (see Table 4.5). Occupational therapists rated participant's adherence to each occupational therapy session, after each session and recorded it on the occupational therapy log. Participants rated their own overall level of adherence with the research assistant as part of the

Participant Questionnaire (see Appendix 14) during the post-intervention outcome measure appointments.

5.2.3.10 How well (actual): Extent of the fidelity and adherence to the delivery of intervention as planned *(Item 12, TIDieR checklist)*

Hoffman et al (2014) define this as:

'If the intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned' (p.7).

The participants who completed therapy (n=16) received an overall level of fidelity of 77% to the provision of occupational therapy as defined in the occupational therapy pathway.

This section delineates the levels of fidelity for each of the eight occupational therapy objectives, information was derived from the occupational therapy logs, provided by the occupational therapists. This is presented alongside the participant (n=14) ratings of their experience of satisfaction of that objective from the participant questionnaire (Appendix 14).

5.2.3.11 Fidelity rating for objective one: Assess occupational performance

The level of fidelity for assessing occupational performance was reported by the occupational therapists as 94% compliant. There were 13 (93%) participants who strongly agreed or agreed that they were satisfied that their occupational therapist listened to what activities and occupations were important to them. The same was reported regarding their occupational therapist asking appropriate questions about their activities and occupations (see Illustrations 5.6 and 5.7).

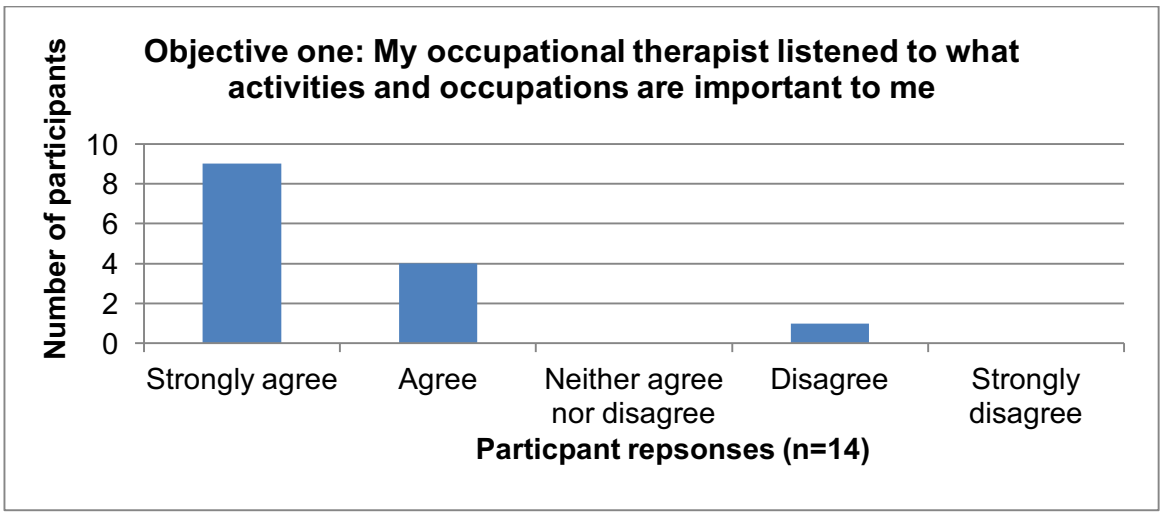

Illustration 5.6 Summary of participants' experience rating of their occupational therapist listening to what activities and occupations were important to them

Illustration 5.7 Summary of participants' experience rating of their occupational therapist asking them appropriate questions about their activities and occupations

5.2.3.12 Fidelity rating for objective two: Formulate occupational needs

The fidelity rating for formulating occupational needs from the occupational therapy logs was 84.36% compliant with providing the key activities in this objective. The majority of participants (n=13, 93%) strongly agreed or agreed that they were satisfied that their occupational therapist helped them to identify what was helping and hindering them to participate in their activities of daily life. Only one participant strongly disagreed, as can be seen in Illustration 5.8.

Illustration 5.8 Summary of participants' experience rating of their occupational therapist helping them to identify what was helping and hindering them to participate in their activities of daily life

5.2.3.13 Fidelity rating for objective three: Set occupational therapy goals

Setting occupational therapy goals had a fidelity compliance rating of 93.57% of the key activities in this objective, which were provided to participants. This alongside objective one (assessing occupational performance, 94%) achieved the highest level of fidelity. Twelve (86%) participant's agreed that they were satisfied that they had set their goals with their occupational therapist (see Illustration 5.9). In contrast one participant neither agreed nor disagreed, and one participant disagreed.

Illustration 5.9 Summary of participants' experience rating of setting their goals with their occupational therapist

5.2.3.14 Fidelity rating for objective four: Plan occupational therapy interventions

The fidelity compliance rating for carrying out the key activities in the planning of the occupational therapy interventions was 90.63%. Illustration 5.10 shows participants ratings of this, with the highest number of responses being from participants (n=8, 57%) who agreed that they were satisfied with their experience of discussing with their occupational therapist, about how they wanted their occupational therapy to be provided. A further four participants (29%) strongly agreed. However two participants were not satisfied with their experience of this.

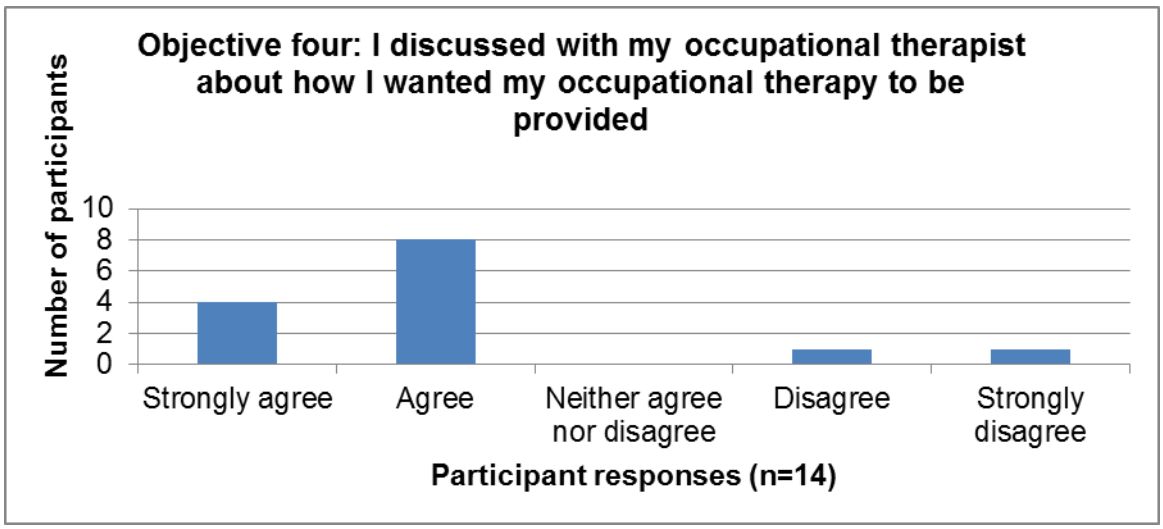

Illustration 5.10 Summary of participants' experience rating of discussions with their occupational therapist, about how they wanted their occupational therapy to be provided

5.2.3.15 Fidelity rating for objective five: Implement occupational therapy interventions

The fidelity compliance rating from the occupational therapists regarding the key activities carried out in the fifth objective for implementing occupational therapy interventions was 77%. This objective was focussed on enabling, "making possible" for the individual to successfully participate in an activity/ occupation meaningful to them. Illustration 5.11 shows that the majority of participants (n=10, 71%) agreed that they were satisfied with their experience that occupational therapy made it possible for them to participate more in the activities and occupations that were meaningful to them. However three participants (21%) neither agreed nor disagreed, with one participant strongly disagreeing.

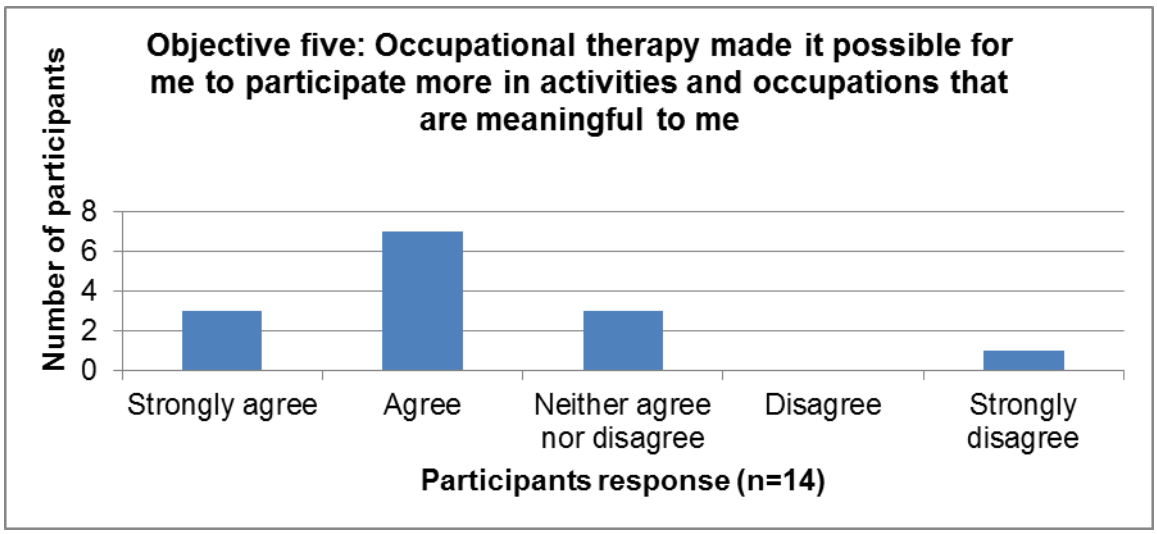

Illustration 5.11 Summary of participants' experience rating of occupational therapy making it possible for them to participate more in activities and occupations meaningful to them

5.2.3.16 Fidelity rating for objective six: Reassess occupational performance

There was a fidelity compliance rating of 78.13%, for the objective of reassessing occupational performance, this was just over one percent above the overall fidelity compliance rating of 77%. Illustration 5.12 shows that seven (50%) of the participants agreed that they were satisfied with their experience of talking to their occupational therapist about their progress with participation more in their activities of daily life and a further five (36%) strongly agreed. One participant strongly disagreed and one was unsure.

Illustration 5.12 Summary of participants' experience rating of talking to their occupational therapist about progress with participating more in their activities of daily life

5.2.3.17 Fidelity rating for objective seven: Review occupational need goals

The key activities that made up the objective of reviewing occupational need goals had a fidelity compliance rating of 81.25%. Participants' experience of satisfaction with reviewing their goals with their occupational therapist is represented in Illustration 5.13. This had the highest positive response from participants' alongside objective one and two, with 13 (93%) participants either strongly agreeing or agreeing; however one participant did strongly disagree.

Illustration 5.13 Summary of participants' experience rating of reviewing their goals with their occupational therapist

5.2.3.18 Fidelity rating for objective eight: Discharge from occupational therapy

The key activities reported as provided by the occupational therapists and that made up the discharge from occupational therapy had the lowest rating of fidelity compliance at 53.13%. Illustration 5.14 shows 10 (74.13%) participants reported that they either strongly agreed or agreed they had more satisfaction with their participation in the activities of daily life most meaningful to them.

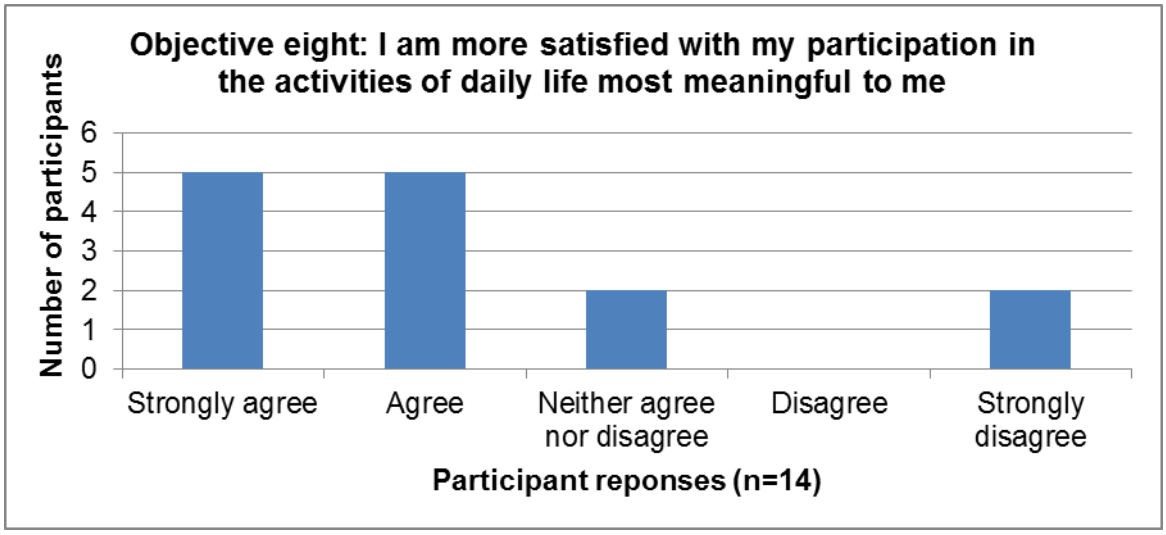

Illustration 5.14 Summary of participants' experience rating of being more satisfied with their participation in activities of daily life most meaningful to them

Adherence ratings

The adherence ratings are summarised in Illustration 5.15 for each of the participants who completed therapy from the perspective of the occupational therapist and the individual participants themselves. The bar chart demonstrates that on nine (56.25%) occasions the occupational therapists rated levels of adherence as being higher than those from the participants. In contrast, two (12.5%) participants rated their adherence higher than that given by the occupational therapists. The adherence ratings were within one point from the occupational therapist and the participant on five (31.25%) occasions.

The biggest rating variation, which was a difference of four was for participant six. Participants one and ten did not score their level of adherence because they did not complete the post-intervention outcome measures and adherence ratings from the occupational therapist for participant ten were missing. Participant eleven did not score a level of adherence and reported this was because there was no plan to stick to.

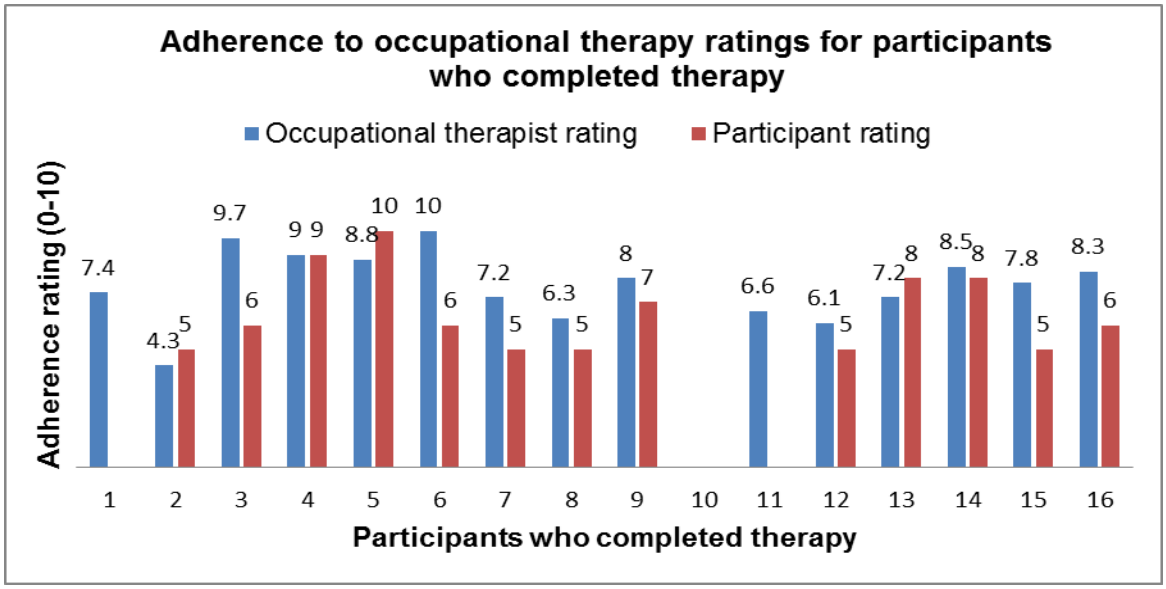

Illustration 5.15 Summary of adherence to occupational therapy for participants who completed therapy

5.2.4 Other interventions

As this feasibility was preparing for a pragmatic RCT, it was therefore carried out in practice and information was collected about what other interventions, participants received during their time in the study. 'Other interventions' was defined as any health or social care interventions that were not occupational therapy. Sturkenboom et al 2012 collected similar data in an RCT feasibility study with people with Parkinson's disease. Table 5.11 provides a summary of what these interventions were.

	Frequency of the provision	Percentage of the total provision
Care co-ordination	47	13.75%
Medication review/ administration	80	23.32%
Crisis contact	42	12.23%
Mental Health Act (CTO)	10	2.92%
Support worker	51	14.87%
Outpatients	6	1.75%
Social inclusion	9	2.62%
Cognitive-behavioural therapy	1	0.29%
Self-directed support	91	26.53%
Inpatient admission	1	0.29%
Social work	2	0.58%
A&E	1	0.29%
Carers support	2	0.58%
Total	343	100%

Table 5.11 Summary of the types of other interventions provided to participants

There were two types of interventions that together made up approximately 50% of the other interventions provided and these were medication review/ administration (provided 80 times, 23.32%) and self-directed support (provided 91 times, 26.53%). A further three interventions made up the majority of the rest of the provision of other interventions and these were: care co-ordination (provided 47 times, 13.75%), crisis contacts (provided 42 times, 12.23%) and support worker input (provided 51 times, 14.85%). Further details are given in Table 5.12 which summarises how many other interventions each participant who completed therapy received.

Participants number	Frequency of other interventions provided	Percentage of the other interventions provided
One	4	1.17
Two	1	0.29
Three	3	0.87
Four	36	10.49
Five	0	0
Six	2	0.58
Seven	160	46.64
Eight	3	0.87
Nine	3	0.87
Ten	3	0.87
Eleven	3	0.87
Twelve	74	21.57
Thirteen	4	1.17
Fourteen	35	10.2
Fifteen	0	0
Sixteen	10	2.92
Totals	343	100

Table 5.12 Summary of the amount of other interventions provided to participants

Participant seven received 160 other interventions, which constitutes 46.64% of the total other interventions provided. Additionally participant 12 received 21.57% of the total other interventions provided and a further two participants received approximately 10% of the total each. All other participants received between 10, 2.92% and zero other interventions over the duration of the study.

5.2.5 Numbers analysed

It is important to state the number of participants included in each analysis (Jarlais et al 2004, Moher et al 2010). There were 16 participants who completed occupational therapy, for whom 14 (88%) post-intervention primary and secondary outcome assessments were available.

5.2.6 Outcomes and estimation

The results for the primary and secondary outcomes of the study are presented in this section for the 14 participants (88%) who provided post-intervention outcome measure data. As the sample size was low, the planned normality testing (see Section 3.8.2) was inappropriate, as the distribution of the means only takes the form of a normal distribution for sample sizes of 30 or more (Bowling 2009). The small sample showed with-in group variability. The data is presented as descriptive statistics as planned (see Section 3.8.1). It also shows the calculated effect size (>0.05) from the Wilcoxon signed rank test (see Section 3.8.2).

5.2.6.1 Primary outcomes

The primary outcome was time use in constructive economic activity and structured activity, measured in hours per week. The results of the outcome variables of time use are presented in Table 5.13. The table shows that at baseline, participants spent on average more time in structured activity than constructive economic activity. The same phenomenon was observed in the post-intervention results, with both the participant's time use in constructive economic activity and structured activity increasing post-intervention.

Primary outcome: Time use (Time Use survey)	**Baseline intervention** *n=14* mean (SD)	**Post-intervention** *n=14* mean (SD)	**Mean difference** *(baseline versus post-intervention)*	**Effect size** ***(p<.05)***
Time use in constructive economic activity (hours per week)	7.53 (13.83)	8.63 (14.4)	1.1	*0.34*
Time use in structured activity (hours per week)	14.04 (15.07)	16.7 (21.82)	2.66	*0.83*
Notes: SD=standard deviation				

Table 5.13 Results for the primary measure; time use

5.2.6.2 Secondary outcomes

The results for the secondary outcomes are presented in three tables: Table 5.14 presents these for participation; Table 5.15 shows the results for self-reported experience of occupational performance and satisfaction with occupational performance and Table 5.16 gives the outcome results regarding health-related quality of life.

The post-intervention outcome data for participation restriction from the P-Scale showed a reduction in participation restriction from baseline to post-intervention. A reduction in participation restriction was also found in the results of the USER-P; however neither were found to be statistically significant *(p>.05)* results. The differences between baseline and post intervention for participation in vocational activity, leisure and social activity were not statistically significant effects.

Secondary outcomes: participation measures (Outcome measures)	**Baseline intervention** *n=14* mean (SD)	**Post-intervention** *n=14* mean (SD)	**Mean difference** *(baseline versus post-intervention)*	**Effect size** ***(p<.05)***
(P-Scale) Participation restriction	26.5 (6.05)	25.79 (15.08)	-0.71	*0.975*
(USER-P) Frequency of participation in vocational activity	1.36 (0.63)	1.71 (1.2)	0.35	*0.157*
Frequency of participation in leisure & social activity	12.57 (6.72)	11.21 (5.51)	-1.36	*0.131*
Participation restriction	13.86 (6.06)	17.21 (7.06)	3.35	*0.139*
Satisfaction with participation	16.93 (9.34)	17.5 (7.47)	0.57	*0.937*
Notes: *P-Scale – Scores above 12 indicate participation restriction; higher score indicate more participation restriction* *USER-P – Higher scores indicate; higher participation frequency, less participation restriction and greater satisfaction with participation* *SD=standard deviation*				

Table 5.14 Results for the participation outcome measures

Self-reported experience of occupational performance and satisfaction outcome results are presented in Table 5.15; as measured with the COPM. The results are presented in the same format as used by Sturkenboom et al (2012) with the mean grade and standard deviation (SD) for experience of occupational performance and occupational performance satisfaction on a (scale of 1-10).

Both self-reported experience of occupational performance and satisfaction with occupational performance showed clinically significant changes; that is that the change scores were, on average, at least two points greater (Law et al 1998).

Additionally both the self-reported occupational performance satisfaction and experience of occupational performance change scores were statistically significant.

Secondary outcomes: Canadian Occupational Performance Measure (COPM)	**Baseline intervention** *n=14* mean (SD)	**Post-intervention** *n=14* mean (SD)	**Mean difference** *(baseline versus post-intervention)*	**Effect size** ***(p<.05)***
Self-reported experience of occupational performance	3.81 (1.53)	6.39 (1.79)	2.58	*0.002*
Self-reported occupational performance satisfaction	2.7 (1.2)	6.49 (1.62)	3.79	*0.001*
Notes: *Each item is rated from a scale of 1-10 (Higher scores indicate greater occupational performance and satisfaction with occupational performance)* *Experience of occupational performance: (1=not able to do it at all, 10=able to do it extremely well)* *Satisfaction with occupational performance: How satisfied are you with the way you do this activity now? (1=not satisfied at all, 10=extremely satisfied)* *SD=standard deviation*				

Table 5.15 Results for the self-reported experience of occupational performance and satisfaction with occupational performance

The secondary outcome data regarding health-related quality of life is presented in Table 5.16. The data is presented in the conventional format for the SF-36, that is, as mean scores (Bowling 2009).

Secondary outcome: Health-related quality of life *(Domains of the SF-36)*	**Baseline intervention *T* scores** *n=14 (mean)*	**Post-intervention *T* scores** *n=14 (mean)*	**Mean difference** *(baseline versus post-intervention)*	**Effect size *(p<.05)***
Physical functioning	53.06	48.02	-5.04	*0.125*
Role-physical	56.7	58.14	1.44	*0.838*
Bodily pain	45.27	56.88	11.61	*0.046*
General health	62.57	56.57	-6	*0.056*
Vitality	44.64	43.57	-1.07	*0.809*
Social functioning	43.57	36.43	-7.14	*0.136*
Role-emotional	41.91	42.38	0.47	*0.824*
Mental health	42.57	47.43	4.86	*0.081*
Notes: The United States 2009 general population norm-based scale has a mean T score of 50 for all domains indicating health related quality of life. Scores below this indicates health burden related to that particular domain (Maruish 2011) *Standard deviation =10 (Maruish 2011)*				

Table 5.16 Results for health-related quality of life

The first four items in Table 5.16 correlate to the physical aspects of health and the last for items correlate to mental aspect of health (Maruish 2011). The results show that four health domains had an improved mean score difference from baseline to post intervention. Of these improved change scores, only those for bodily pain were statistically significant. The results also show that the other four health domains had a decrease in the mean score, indicating an increased health burden.

Self-evaluated transition, which asks participants to rate the amount of change they experienced in their health in general over a one year period, also showed a positive change in the overall mean score and it was statistically significant.

Secondary outcome: Health-related quality of life *(Domains of the SF-36)*	**Baseline intervention *T* scores** *n=14* *mean (SD)*	**Post-intervention *T* scores** *n=14* *mean (SD)*	**Mean difference** *(baseline versus post-intervention)*	**Effect size *(p<.05)***
Self-evaluated transition: mean (SET)	3.07 (1.3)	2.38 (1.55)	0.69	*0.026*

Table 5.17 Results for health-related quality of life; SET

5.2.7 Occupational therapists effectiveness rating of the occupational therapy intervention

Occupational therapists gave a rating of the effectiveness of therapy at the end of the intervention period (on a scale of 0-10, 0=not successful to 10=very successful), these results are shown in Illustration 5.16. The Illustration presents these rating scores of effectiveness, these ranged from two to nine. Occupational therapists gave an effectiveness rating of five or more on eleven occasions and the mean effectiveness score was 6.36.

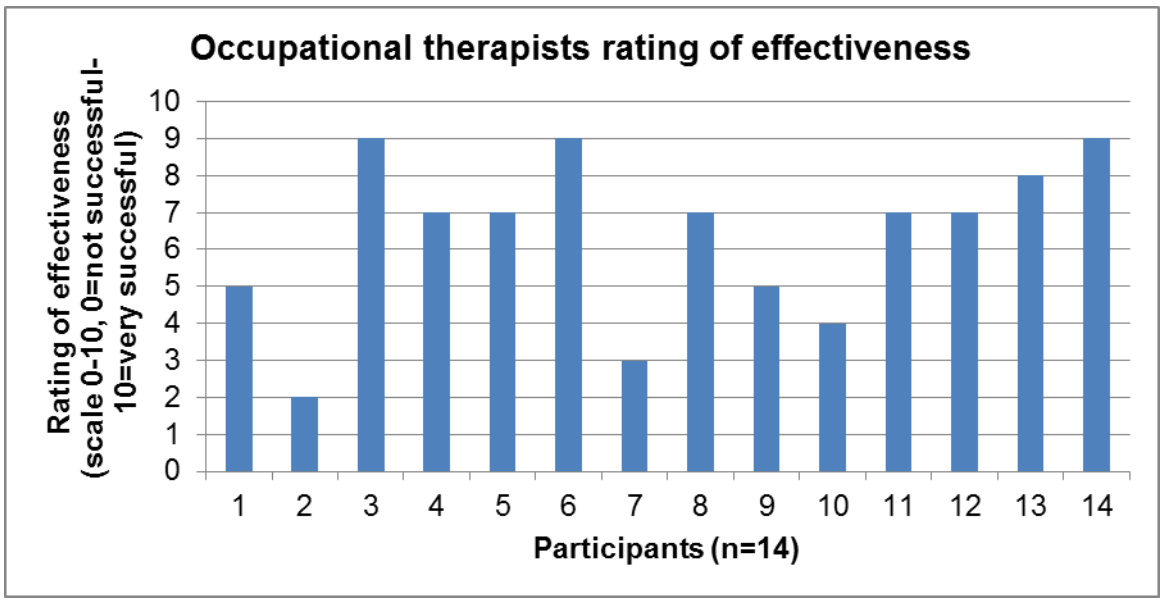

Illustration 5.16 Occupational therapists rating of effectiveness

The participant's (n=14) rating of effectiveness was reported as part of the findings regarding fidelity (see Illustration 5.12).

5.2.8 Ancillary analysis

No additional ancillary analysis was undertaken separate to that planned.

5.2.9 Harms

It is recommended that all important harms or unintended effects are reported (Moher et al 2010). No adverse effects were reported regarding participants during the study.

5.3 Summary

The study outcomes have shown that of the 36 potentially eligible participants for the study, 20 were recruited, 16 completed therapy and there were baseline and post-intervention outcome measures for 14 participants (See Section 5.2.1). Baseline characteristics (see Section 5.2.2) were presented as descriptive statistics due to the small sample size, the key difference was the

type of diagnosis of psychosis. Within the group who completed therapy, the majority of participants had a diagnosis of non-affective psychosis, whereas the reverse was shown for those participants who did not complete therapy. Those who withdrew from therapy also had lower time use scores at baseline on both constructive economic activity and structured activity than those who completed therapy.

The occupational therapy intervention provided was reported using the *TIDieR checklist* (Hoffmann et al 2014) and it showed that all of the procedures outlined in the occupational therapy pathway (see Appendix 13, p.365) were utilised by the occupational therapists (see Section 5.2.3.2). Differences were reported regarding the characteristics of the occupational therapists providing therapy, from the two centres (see Section 5.2.3.3). There were differences in: gender, banding, age, length of time since qualifying as an occupational therapist, team setting and the amount of time that their everyday clinical caseload was spent providing occupational therapy. The occupational therapy was provided face to face (see Section 5.2.3.4) and the majority of this was in the participants own homes (see Section 5.2.3.5). The mean number of occupational therapy sessions per participant was 11.75 (6.58), the mean duration was 19.06 (6.79) weeks and the mean intensity was 65.15 (23.55) minutes, for those who completed therapy (see Section 5.2.3.6). The occupational therapy intervention was tailored to each participants individual needs (see Section 5.2.3.7). The occupational therapy intervention log (see Appendix 13, p.399) captured 98% of the occupational therapy provided and occupational therapists provided non-occupational therapy in 21 (12%) of the occupational therapy sessions.

Fidelity was monitored and supported throughout the study and the actual procedures for measuring fidelity and adherence were followed as planned (see Section 5.2.3.9). The overall level of fidelity to the occupational therapy intervention was 77% (see Section 5.2.3.10). The fidelity rating for each of the occupational therapy objectives was presented, with the highest level of fidelity being reported by the occupational therapists as being for objective one; assess occupational performance and objective three; setting occupational therapy goals. The majority of participants agreed that this had happened. The adherence rating from the participants and occupational therapists (using a scale of 1-10) showed that they gave it a rating within one point, on seven out of the thirteen full sets of adherence ratings available. There was missing data from three participants and one occupational therapist. The biggest reported variation was 3.7 points on the scale.

'Other interventions' were provided to participants from other sources, over the duration of the study on 343 occasions (see Section 5.2.4). Approximately 50% (172 interventions) were made up of either: medication reviews/ administration or self-directed support. One participant received a total of 160 (46.44%) of the total 'other interventions' provided, another participant received approximately 20% of the total and two more participants received another 10% each.

The primary and secondary outcome measures were presented as descriptive statistics and with calculated effect sizes (see Section 5.26); however not generalizable to the wider population. The baseline and post-intervention scores for the primary outcome of time use in constructive economic activity and structured activity both showed increased scores; however this was not statistically significant *(p>.05)* (see Section 5.2.6.1).

Participation restriction scores showed a reduction in restriction on both the USER-P and the P-Scale and increased satisfaction with participation on the USER-P; however these were not shown to be statistically significant *(p>.05).* Self-reported experience of occupational performance *(p=.002)* and satisfaction with occupational performance *(p=.001)* had clinically significant and statistically significant improvements (p<.05).

Health-related quality of life data was presented as mean scores and compared against the means for the US general population. Four health domains showed improvements from the baseline and post-intervention scores and only bodily pain was shown to be statistically significant *(p=.046) (p<.05).* The other four health domain scores indicated that health burden had increased; however these changes were not found to be statistically significant *(p>.05).* Self-evaluated transition which rates the amount of change the participants have experienced in their health in general increased from baseline to post-intervention and this change was found to be statistically significant *(p=.026) (p<.05).*

The occupational therapists rated the effectiveness of occupational therapy on a scale of 1-10 and the mean score of effectiveness was 6.36. No ancillary analysis was undertaken and no harms were reported from the intervention. These study outcome results will next be interpreted and discussed together with the process outcome results (Chapter six) in the discussion, Chapter seven.

Chapter 6 Feasibility study results: process outcomes

6.1 Introduction

This results chapter presents the process outcomes of the study. The first part of the chapter reports the findings related to objective six of the study:

- How occupational therapy enables people with a diagnosis of psychosis to participate in activities of everyday life (Section 6.3)

The second part of the chapter (from Section 6.4) presents results related to four other process outcome objectives of the study, (measurement of fidelity and adherence has already been reported in Sections 5.2.3.9 and 5.2.3.9) namely:

- A valid description of occupational therapy for a pragmatic RCT
- Utility of the method to measure fidelity
- Utility of the method to measure adherence
- Reliable and valid method of measuring participation, with utility for a pragmatic RCT

To achieve triangulation of the data, the results presented have been gathered and analysed from the occupational therapist focus groups (see Section 3.6.8), the participant questionnaire (see Appendix 14) and qualitative data from the final occupational therapy logs (see Appendix 13, p.399). For clarity the origin of each of the data sets will be indicated within the section it is presented.

6.2 Results: process outcomes

6.2.1 Occupational therapist focus groups

Two focus groups were held (one in each centre); these were carried out after all the occupational therapy interventions were complete. The focus groups included occupational therapists who had delivered occupational therapy and the occupational therapy clinical specialist who had provided supervision and carried out the fidelity checks. The focus group in centre one included all the occupational therapists who had provided therapy (no occupational therapy clinical specialist because that was also the researcher) (n=3). In centre two (n=4) one occupational therapist was unable to attend and the occupational therapy clinical specialist also contributed. The researcher facilitated the focus groups, using the focus group conversation guide (see Appendix 15); each lasting approximately one and a half hours. The focus groups were recorded and transcribed. The data was analysed using the content analysis approach described by Elo and Kyngas (2007); an example of this analysis can be found in Appendix 19. It generated the following main categories about occupational therapy in the study:

- *Every time a person-centred contact* (see Section 6.3.1)
- *Occupational needs formulation was the focal point* (see Section 6.3.2)
- *Enablement to do more, be active and be more* (see Section 6.3.3)
- *Doing occupational therapy research in practice* (see Section 6.4)

The general and sub-categories of each of the main categories are outlined in tables (6.1, 6.2, 6.3a, 6.3b, 6.8a and 6.8b) and indicated in the main text in *italics*; categories are delineated further in each of the sections. The terms service user and participant are used interchangeably because this is representative of the focus groups language.

6.3 Occupational therapy with individuals with a diagnosis of psychosis

The majority of the data generated through the occupational therapist focus groups concerned the relationship between occupational therapy and how it enabled individuals with a diagnosis of psychosis to participate more in their activities of daily life. Therefore three of the main categories and the associated general and sub-categories are presented in this section. The first main category reported on is: *Every time a person-centred contact*, in Section 6.3.1 this is presented together with participant's feedback about their experience of their occupational therapist. The main category of: *Occupational needs formulation was the focal point* is presented in Section 6.3.2. *Enablement to do more, be active and be more* is the main category presented in Section 6.3.3. The data in Sections 6.3.4 and 6.4.5 adds further to the picture given through the main categories and includes data generated from the participant questionnaire and the last occupational therapy log for those participants who completed therapy. Section 6.3.4 also presents the enablers and facilitators to participation in the activities of daily life from the perspective of the participants and occupational therapists. The final section, that is Section 6.3.5 presents the hurdles and hinders to participation in the activities of daily life from these two different perspectives.

6.3.1 Every time a person-centred contact

This main category emerged as an approach that was adopted whenever the occupational therapist met or spoke with the participant. *Every time a person-centred* contact summarises three underpinning general categories, which were: *engagement, work from where the individual is* and *non-judgemental* and *compassionate approach*, these categories and the sub-categories that make

these up are presented in Table 6.1 and are described in more detail throughout this section. "*Italics"* with speech-marks are used throughout to indicate direct comments, quoted with the relevant coded occupational therapist, centre and page number of the focus group transcription in brackets as (OTxCx.x).

Sub-category	General category	Main category
Has barriers and can fluctuate	*Engagement*	*Every time a person-centred contact*
Creativity to create engagement		
Willing and ready to engage		
Engage on the individuals agenda		
Engaged with individual and their family		
Therapeutic relationship was fundamental		
Every time reconnect with the individual	*Work from where individual is*	
Appreciating what's important to the individual		
Go with the individuals priority		
Reflective conversations about progress		
Person-centred approach enhanced the process		
Respectful of where the individual is at	*Non-judgmental and compassionate approach*	
Really listening and understanding		
Get a clear idea of what their wants and needs are		
Enable the individual to come to their own conclusions		

Table 6.1 Focus group main category: Every time a person-centred contact

Engagement

Engagement was frequently referred to and it was acknowledged that this can and does fluctuate and sometimes this is outside the participant's control, for example financial. This was captured as having creativity to create engagement,

"*we had to be more creative in how we kind of engaged with each other and how she wanted to move forward really around her goals"* (OT1C2.13).

The importance of the participants to be *willing and ready to engage* was associated with greater progression. Whilst engaging on the individual's agenda also influenced engagement; respecting what the participants saw as the problem was a strong feature too. *"The only way I could actually engage with him was on his agenda"* (OT1C1.4). Engagement also included involving the family in the intervention if it was needed and the participant was in agreement. Creating engagement was underpinned by creating and establishing a strong therapeutic relationship.

Work from where the individual is

A strong feature of this general category was *every time reconnect with the individual*…

"it was almost kind of reconnecting with the person and kind of checking out where they were at and where they needed to go" (OT3C1.2).

Approaches to appreciating what's important to the individual were described as "*understanding a little bit of their story"* (OT3C1.14) and "*walking in their shoes a little bit"* (OT2C1.12). The importance of going with the participant's priority in sessions was a dominant feature and described by one occupational therapist as;

"*being prepared to actually go straight forward towards that or slightly detour or slightly backtrack if you need to, to kind of get where you need to go in the long run really*" (OT3C1.2).

Reflective conversations about progress with participants was frequently cited and involved asking questions to the participants about what had and hadn't worked and what might work better next time? These reviewing conversations

mostly occurred at the beginning and end of sessions, encompassing goals, described by one occupational therapist as;

"*slowly, gently, testing things out you know and the person having a better understanding of themselves*" (OT1C1.2).

It was recognised that this *person-centred approach, enhanced the process*.

Non-judgmental and compassionate approach

Taking a *non-judgemental and compassionate approach* involved being *respectful of where the individual is at*. There were many facets to this sub-category, which seemed to be based on a premise as described with this participant;

"*there's no judgement there, he was able to express himself quite safely to be able to move forward really"* (OT1C".14).

It also involved the occupational therapists "*accepting and tolerating different realities"* (OT2C1.12). One occupational therapist described how they worked with the service users beliefs and change came along:

> "*The starting point was "I'm not gonna go and engage in any activity other than if it's in a day centre or with people who have similar experience to me"…So that's the starting point but I didn't kind of challenge that, you know, I didn't go in at the start and challenge that, I just kind of worked with it really. And working with it, that change kind of came along"* (OT1C1.11).

"Really listening to the person and understanding where they're coming from" (OT3C1.14) was important and involved "*being beside* (OT2C1.17)*"* the participants. Whilst enabling the person to come to their own conclusions was described as being achieved through applying the skilled use of patience until they get the realisations for themselves.

Participants experiences of their occupational therapist

As part of the participant questionnaire, participants rated how respectful their occupational therapist was and how much that they felt that their opinion mattered. This is presented in Illustration 6.1, fourteen participants answered this question, with 13 (93%) agreeing that their occupational therapist was respectful and that their opinion mattered; 10 (63%) participants of which strongly agreed. One participant disagreed with this experience.

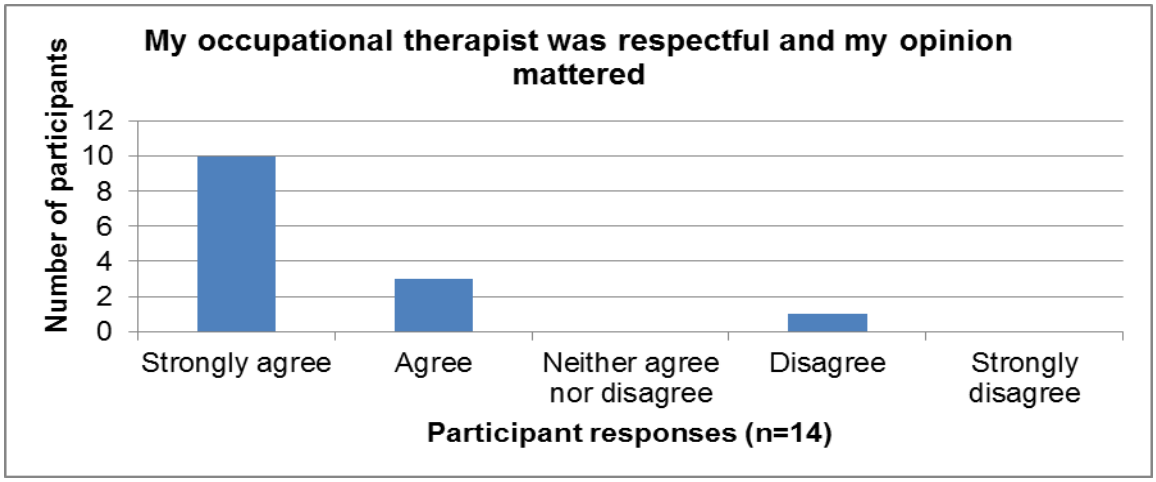

Illustration 6.1 Participant responses: My occupational therapist was respectful and my opinion mattered

Illustration 6.2 shows that all of the participants (n=14) that completed the participant questionnaire rated their occupational therapist as friendly and approachable, with 11(79%) strongly agreeing.

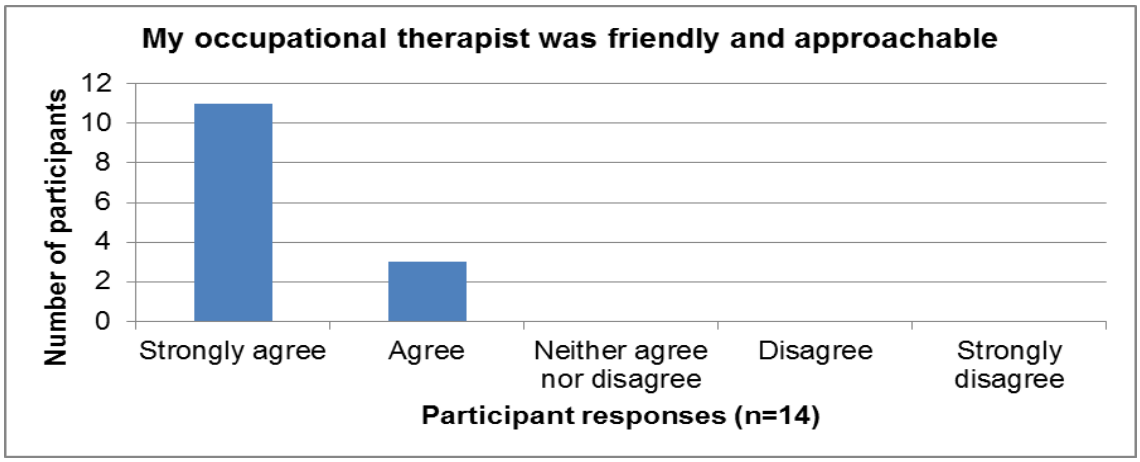

Illustration 6.2 Participant responses: My occupational therapist was friendly and approachable

6.3.2 Occupational needs formulation was the focal point

The occupational needs formulation was recognised as a focal point for the occupational therapy intervention. This is a main category from the focus groups which had two connected general categories: *occupational needs formulation* and *collaborative process with the service user.* A summary of these categories and the related sub-categories are given in Table 6.2.

Occupational needs formulation

The occupational needs formulation was described as being the

"*analysis of the person, the environment and the changing landscape within the environment and their occupations*" (OT3C1.14).

It included participants

"*understanding how their mental health separated them really from community, the society"* (OT1C1.11).

Identifying occupational need aspirations and strengths was a feature of the occupational need formulation*,*

"it's also about identifying your strengths, isn't it, because you're showing what those strengths are, and you can use those strengths to get to where they want to be" (OT3C2.16).

The formulation appeared to be embryonic in nature and was frequently re-visited and always growing and developing. It was identified as an important part of enabling participants to reflect on and evaluate their progress and subsequently adapt the formulation. Both the occupational needs assessment and formulation were recognised as key components of the intervention that clearly differentiated occupational therapy from support worker interventions which involve activities.

Sub-category	General category	Main category
Analysis of the person, environment and the changing landscape of the environment and occupations	*Occupational needs formulation*	*Occupational needs formulation was the focal point*
Identify occupational need aspirations and strengths		
Formulate at the beginning		
Occupational need formulation, revisiting, growing and developing		
Occupational need assessment and formulation makes it different to support worker interventions		
Catalyst for service user insight and change	*Collaborative process with the service user*	
Collaboration to produce occupational formulation		
Crucial to specify our shared agenda.		

Table 6.2 Focus group main category: Occupational needs formulation was the focal point

Collaborative process with the participant

The occupational needs formulation was a focal point for the occupational therapy intervention which,

"was very much a collaborative negotiating process, all along the way to discuss that kind of constant planning and checking with the service user" (OT3C1.11).

There were numerous examples about how the occupational formulation process had been the catalyst for service user insight and change, including the following:

- *"…was able to see positive outcome"* (OT1C2.6)
- *"…increased understanding they're then making a lot of changes themselves"* (OT2C2.6)
- *"…drawing this guy out of this endless cycle of you know rumination and inactivity "* (OT2C1.5)

- *"…people can see… kind of make the links themselves really, and understanding the different areas and which ones to kind of prioritise"* (OT1C1.5).

One occupational therapist described that a,

"*lot of people can't see what the barriers are until you have that discussion. Sometimes just that light bulb moment is the thing that helps with that motivation to change, because they can actually see what the hurdles are"* (OT3C2.16).

It was stressed that it was "*crucial to specify our shared agenda"* (OT1C1.5), between the participant and occupational therapist. The occupational formulation was used to help prioritise therapy, set the direction and clarify what was going to be achieved in that particular day's session.

6.3.3 Enablement to do more, be active and be more

The main category from the focus groups, from the largest portion of the data, was *enablement to do more, be active and be more.* This was made up of six general categories and because of the size of the data this has been presented in two tables, Table 6.3a, followed by Table 6.3b.

Table 6.3a has three general categories which were: *co-creating a positive future, moving recovery forward* and *outcome measurement process 'more than it says on the tin'.*

Co-creating a positive future

Believing the service user can move to a more positive future was described as the occupational therapist having a positive attitude about what was possible and what the participant was capable of achieving. Sharing thoughts with participants included "*you can do more, there is more"* (OT1C2.17) and "*you can move forward"* (OT2C2.15). *Having choices and exploring options* was core to this, as was working with the participants strengths to achieve the goals that

they wanted. This process was articulated as being a "*collaborative negotiating process"* (OT3C1.11), working "*hand in hand"* (OT1C1.13) with the participant and using questions such as: "*What are we going to achieve today?"* (OT3C1.2) and

"how are we going to set about achieving what we are going to do today?" (OT3C1.2).

"This shared decision making all along the journey" (OT3C1.3) involved the occupational therapists being clear about what they could offer and what particular things the participants would bring.

Sub-category	General category	Main category
Believing the service user can move to a more positive future	*Co-creating a positive future*	*Enablement to do more, be active and be more*
Having choices and exploring options		
Using strengths		
Collaborative negotiating process		
Shared decision making along the journey		
Big goal at top and lots of little goals in between	*Moving recovery forward*	
The 'just right challenge'		
Graded activity to achieve task		
Identifying and exploring barriers to participation, to overcome		
Responsive to each individual		
Enabling the person to do, not doing for		
Enable to use skills and resources to make changes		
Adapted environment		
Regular honest reflective conversations about wants and progress		
Better outcomes, greater adherence	*Outcome measurement process ' more than it says on the tin'*	
COPM demonstrated good outcomes		
Gaining insight through collaborative change conversations		
Inputs not always clearly specify outputs		

Table 6.3a Focus group main category: Enablement to do more, be active and be more

Moving recovery forward

There was a lot of discussion about *moving recovery forward* and a strong theme connected to a continuous focus on movement. It involved participants having broad goals and session specific goals. The "*just right challenge"* (OT3C1.12) was used synonymously with "*pitching the right activity"* (OT3C1.16). It was described as being achieved through understanding whether the challenge was about skills, roles or occupations and then having skilfully, crafted challenges that create the "*right thing to participate in at that moment"* (OT3C1.16). Graded activity was a part of the "*just right challenge"* (OT3C1.12) and included using mini goal setting. Identifying and exploring the barriers to participation that needed to be overcome was also part of this recovery movement. Ensuring that the occupational therapy was *responsive to each individual* was a feature; this came in part from the knowledge of the person, their environment and observational assessments whilst they were performing tasks. Enabling the person to do, not doing for was recognised as enabling the participants to move forward in many ways, including:

- *"shopping independently"* (OT2C1.15)
- *"to manage his own money"* (OT2C1.15)
- *"do his own laundry"* (OT2C1.15)
- *"attending a leisure centre and engaging in a mainstream activity"* (OT1C1.11)
- *"self-care improved"* (OT1C1.8)
- *"having some kind of structure"* (OT1C2.14)
- *"doing more of what they had always wanted"* (OT1C1.12)

This movement towards more independent living was created through enabling participants to use their own skills and resources to make changes. It included adapting the environment, both social and physical; whilst also being facilitated through *regular, honest reflective conversations, about wants and progress.*

Outcome measurement process 'more than it says on the tin'

This general category was created to capture the range of elements to the outcome measurement process, which was described as achieving much more than simply measuring change, that is 'more that it says on the tin'. A view shared by many of the occupational therapists was "*better outcomes had the greater adherence"* (OT2C1.17). The COPM was identified as demonstrating good outcomes to both the occupational therapists and participants. Participants appeared to gain insight through collaborative change conversations it was the 'vehicle' for having in-depth, change conversations with participants, which included what had happened to create progress. An anomaly was that inputs from occupational therapy on specific goals did not always clearly specify outputs.

The second table describing *enablement to do more, be active and be more* includes three more general categories, which were: *previous way of being, empowerment* and *global improvements 'knock on effect'*. The first general category describes where participants where when they started occupational therapy and the second two general categories emerged as valued areas where the occupational therapists witnessed positive change in participants.

Previous way of being

The majority of participants described generally negative experiences and feelings at the start of the study. Some were fearful and fixed about what was possible and struggling to function and maintain their own homes. Some participants were,

"*unused to sort of expressing their opinions, preferences and having choices"* (OT2C1.9).

One participant was described as having "*disempowered passivity* (OT2C1.17). Some participants had skills deficits that were impacting on tasks and one participant being "*actively opposed to medical treatment"* (OT2C1.6). Some participants were living and trying to participate in unsupportive/ disabling environments. Inactivity was a feature and the barriers to participation were wide-ranging, these included; lack of choice in community activities, limited public transport, social environment at home, family and professionals reinforcing negative beliefs about capabilities, safety of local area and mental health diagnosis for a number of years and related beliefs that couldn't move forward.

Sub-category	General category	Main category
Fearful and fixed about what was possible	*Previous way of being*	*Enablement to do more, be active and be more*
Struggling to function and maintain own home		
Unused to expressing opinion, preference and choice		
Skills deficits impacting on tasks		
Actively opposed to medical treatment		
Unsupportive/ disabling environments		
Inactive		
Barriers to participation wide -ranging		
Acted more with independence	*Empowerment*	
Individual responsibility to contribute and make decisions		
Raised expectations		
Improvements transferred to other areas of life	*Global improvements 'knock on effect'*	
More able to cope		
Feeling better about self		

Table 6.3b Focus group main category: Enablement to do more, be active and do more

Empowerment

During the occupational therapy sessions participants began to act with more independence and to take more individual responsibility to contribute and make decisions. For example:

> *"…he's changed his home and made it a lot better, more liveable, and he's applied for voluntary work, whereas before there was a lot of issues going on, he wasn't doing anything for his home"* (OT1C2.14).

There was a theme of *raised expectations* through having been involved in occupational therapy; one occupational therapist reported that one participant rated her COPM lower at the end of therapy (despite apparent improvements) than she did at the start of therapy. When asked about the reasons for this, the participant reported;

"*Well I expect I can do more now so I'm less satisfied with where I'm up to because I know I can get further"* (OT2C2.10).

Global improvements 'knock on effect'

Global improvements were reported which appeared to be "*knock on effects*" (OT2C1.7) from occupational therapy with participants. Improvements transferred to other areas of life, one occupational therapist described;

"… we've set some goals in a particular area but for whatever reason they felt more motivated, more confident, more able, to do things in other areas" (OT1C1.8).

Participants reported that they were more able to cope and one reported; *"I just feel a bit better about myself"* (OT1C1.8).

6.3.4 Enablers and facilitators to participation in the activities of daily life

The responses from participants about what was the biggest factor in enabling them to participate more in activities of daily life most meaningful to them are presented in Table 6.4. As with the presentation of the focus group analysis

both the direct occupational therapists quotes are represented in italics, as are the participants. Thirteen participants answered this question as part of the participant questionnaire; responses are grouped together to demonstrate the key factors in enabling participants to participate more in activities of daily life most meaningful to them. Responses are written as recorded on the participant's questionnaire to remain authentic. Six (40%) participants identified that working with their occupational therapist was the biggest factor, this included: *giving confidence to go out, overcoming anxiety, help to tidy their home, talking through things and engaging in activities that they had identified*.

The biggest factor in enabling more participation in the activities of daily life most meaningful to you (n=13)
Working with my occupational therapist (n=6)
Having OT there to educate how to overcome anxiety; OT gave me confidence to go out. My OT helped me tidy my home up *Being listened to and being able to talk things through with my OT frequently. She was very client-centred.* *Working with Occupational therapist and engaging in the activities that I've identified* *Receiving more help from my occupational therapist and support worker* *Working with my occupational therapist*
Having support and encouragement, gaining insight (n=3)
Talk through the problems and analysing my progress each time we met – gradual process seen *Made me realise how to get out of this rut* and *made me realise how much I needed to do. Support and encouragement throughout the process*
Taking control and independent living (n=3)
Introduced me to a couple of places to reduce my social isolation *Breathing exercises that she taught me – it helped me copy with my anxiety* *Managing and sorting new bus card*
Motivation (n=1)

Table 6.4 Participants perspective on the biggest factor in enabling more participation in activities of daily life

Three (23%) participant's responses related to having support and encouragement and gaining insight through the process, for example: made me realise how to get out of this rut. A further three (23%) participants cited elements that were associated with taking control and gaining more independence with daily living and one participant identified motivation as the biggest factor to enabling more participation.

The occupational therapists also identified what factors had hindered the success of the occupational therapy intervention with each of the participants they had worked with; the main factors identified are summarised in Table 6.5.

Factors that facilitated success of the occupational therapy intervention
Development and establishment of a therapeutic relationship
Honest discussions/ Open discussion *Therapeutic use of self/ You being reliable/ Having trust in you*
Participant motivation, engagement and commitment
Good engagement from participant *Service user's commitment to process/ Client's motivation to change*
Engaging with an acceptance of differing realities
Avoiding argumentative debate regarding causal factors, diagnosis and the rationale for medical treatment *Boundary setting with service user*
Collaborative and effective goal setting
Clear goals/ Realistic goals/ Achievable goals *Collaborative goal planning regarding identification of meaningful occupation/ Client centred goals*
Occupational need formulation
Developing an occupational formulation which enabled us to anticipate, accept and overcome barriers to participation/ Identifying and discussing barriers *Client-centred formulation*
Activation
Activation of independent problem solving through coaching and environmental prompts
Table 6.5 Occupational therapists perspective on the factors that facilitated success of the occupational therapy intervention

Use of occupation meaningful to the participant
Identifying important factors to participant's life/spirituality/ Past experience in occupation gave base line to build on, and increased opportunity to make achievements
Graded activities and support at participants level
Graded support, agreed collaboratively/ Went at service user's own pace *Sensitive grading to create optimal degree of challenge to maintain motivation and progress*
Supportive social environments
Course used by other service users, eased participants concerns regarding stigma *Staff at the community centre, were supportive and non-judgemental; made participant feel at ease attending* *Working effectively with the human environment i.e. Engaging both service user and parents.*
Positive re-enforcement
Reflective discussion, especially on strengths and coping strategies.
Close liaison and working with care co-ordinator
Appointment/ intervention structure
Regular appointments/ Weekly contact/ Length of contact (1hr)

Table 6.5 Occupational therapists perspective on the factors that facilitated success of the occupational therapy intervention (continued)

The full details of the occupational therapists comments can be found in Appendix 20. Developing and establishing a therapeutic relationship involved being honest, open and creating trust; the elements of this factor were identified on eight occasions. Participant motivation, engagement and commitment to the process, was another strong factor which contributed to the success of the occupational therapy. There was recognition that sometimes engagement was maintained by accepting different realities between the occupational therapist and the participant. Collaborative and effective goal setting was frequently (n=10) quoted as being a key factor in the success of the intervention. The contribution of the occupational need formulation was described as: *Developing an occupational formulation which enabled us to anticipate, accept and overcome barriers to participation.* The use of occupation meaningful to the participant was identified as part of the success of occupational therapy. The grading of activities was described as being through collaboration with the

participants to achieve the *just right challenge;* supporting participants to do more. Positive re-enforcement contributed to the participant's achievements. The contribution of the occupational therapists approach was quoted as creating *activation to more independent problem solving, through coaching and environmental prompts.* Particular environment prompts/ supports came from the social element of environments including: parents, other service users and community centre staff. Additionally close liaison with the participants care co-ordinator was also quoted as key to success.

6.3.5 Hurdles and hinders to participation in the activities of daily life

The responses from participants about what the biggest hurdle to participating more in activities of daily life most meaningful to them are presented in Table 6.6. These responses were grouped together in the same manner as those in Table 6.4. The most frequently cited hurdle to overcome in its own right was related to motivation, which four participants (29%) identified. Whilst physical health was cited most frequently (n=5, 36%); this consisted of it as a hurdle on its own (n=2, 14%) and together with mental health problems (n=3, 21%). Anxiety (n=2, 14%) and trusting people (n=2, 14%) were also identified as hurdles and one participant reported that confidence was their biggest hurdle to participating in the activities of daily life most meaningful to them. All of the hurdles identified by participants were related their own state of health and well-being.

The biggest hurdle to participating more in activities of daily life most meaningful to you (n=14)
Motivation (n=4)
My motivation levels/ Motivation/Motivation/ Poor motivation
Physical and mental health problems (n=3)
Health and anxiety – related fatigue and change in medication *Anxiety, confidence and physical pain* *My physical and mental health problems*
Physical health (n=2)
Biggest hurdle was related to limitations to physical health *Physical health*
Anxiety (n=2)
Anxiety *Coping with my anxiety, and getting out on my own*
Trust (n=2)
Trusting people and getting comfortable, but got through this *Coping with symptoms associated with psychosis. Learning to trust someone*
Confidence (n=1)

Table 6.6 Participants perspective on the biggest factor in enabling more participation in activities of daily life

The main factors that occupational therapists identified as hindering the occupational therapy intervention are summarised in Table 6.7. All of the occupational therapists responses in relation to this question can be found in Appendix 21. It was recognised that environmental factors hindered the success of the occupational therapy interventions; this included social support, physical and financial factors. *Limited ambitions and expectations of carers* and *limited social support outside services* were both sited as contributory factors. The physical health of participants was identified as a factor affecting success; with the side effects of medication causing drowsiness also contributing to this. Participant factors concerning their attitudes, beliefs and mental health were frequently recognised, some of these aspects related to *negative self-belief* and *limited ambitions and expectations of service user*. Other factors were

connected to participants mental health, motivation was a key feature; however it was recognised that sometimes this was due symptoms of their diagnosis (*negative symptoms*). *Service user's cognitions* and level of *insight* were also cited. Social stressors were also recognised as affecting, the success of the occupational therapy, as well as historical experiences of trauma and personal bereavements. Participants having well established roles and routines was, also sometimes a factor affecting progress with therapy. Breaks or delays in therapy seemed to cause disruption; however sometimes this was in response to the changing needs of the participants. It was reported that being the care co-ordinator and the delivering occupational therapy to the same participant caused some issues, particularly in relation to monitoring and managing conditions set by the Mental Health Act. Having support from the multi-disciplinary team (MDT) to deliver occupational therapy and the administration related duties required alongside therapy were also seen as factors affecting provision of occupational therapy.

Factors that hindered the success of the occupational therapy intervention
Environmental: social support
Limited ambitions and expectations of carers/ Limited social support outside services *Changes in staff within the housing project*
Environmental: physical and financial
Environmental factors – location and resources *Financial restrictions*
Participant factors: physical health
Service user's physical health *Commenced Clozapine which required monitoring and caused some drowsiness*
Participant factors: established roles and routines
Rigidity in routine, difficulty with spontaneity/ Well established familial roles/routines *Overwhelming task*
Table 6.7 Occupational therapists perspective on the factors that hindered the success of the occupational therapy intervention

Participant factors: attitudes, beliefs and mental health
Motivation (negative symptoms)/ Level of motivation to change/ Desire to change *Self-focus on illness when experiencing changes in emotion* *Service user's cognitions/ Insight* *Negative self-belief/ Limited ambitions and expectations of service user*
Participant factors: social
Social stressors *Social factors within the family/ Estrangement from family/ Enforced marriage* *Historical trauma/ Recent bereavement / Loss of support from deceased girlfriend*
Breaks or delays in therapy
Had to go with support time and recovery worker because of risk *Because of Clozapine had a break in therapy* *Delay in CBT to support him to work on cognitions alongside occupational therapy intervention*
Conflict of between occupational therapy and care co-ordination roles
Care coordination responsibilities resulted in an obligation to seek to renew and reinforce restrictive CTO conditions
Securing MDT support to maintain clarity of OT role and purpose
Increased administrative burden of CPA and OT paperwork

Table 6.7 Occupational therapists perspective on the factors that hindered the success of the occupational therapy intervention (continued)

6.4 Doing occupational therapy research in practice

The fourth main category was *doing occupational therapy research in practice* was made up of six general categories and therefore due to the size of the data it is presented in two tables, firstly Table 6.8a, followed by Table 6.8b.

Table 6.8a consists of three general categories, which are: *recruitment and enrolment, utility of the occupational therapy log* and *the occupational therapy log revealed the intricacies of occupational therapy practice.*

Recruitment and enrolment

The occupational therapists experienced *recruitment challenges* these included: not enough time to recruit participants and not everyone met the inclusion criteria or wanted to be involved. The research assistants were doing clinical

and research assistant work which was identified as sometimes slowing the recruitment process. It was recognised that recruitment needed to *"be quick and slick and responsive"* (OT3C1.18). Strategies for *making enrolment even more successful* were suggested, which included: having the option of having the initial occupational needs screening conversation either via the telephone or face to face. It was also suggested that the occupational therapist could potentially going on a home visit with the care co-ordinator, to have the initial conversation about the study. There were particular challenges identified regarding *being a research assistant who happens to be an occupational therapist,,* the most common being not to start carrying out the occupational therapy assessment when completing the baseline outcome measures with participants.

Utility of the occupational therapy log

The use of the occupational therapy log to record the occupational therapy intervention was reported as being *"pretty straight forward to do"* (OT1C1.3), and *"it was kind of structured, it was logical, it was a concept I was familiar with"* (OT3C1.2). However it was also described as taking additional time to complete, more than just doing clinical notes. It was consistently reported that the occupational therapy log captured *"what you've actually delivered in that session"* (OT4C2.2). The experience of using the intervention specification in practice for the study was described as:

> "*Certainly in my experience in terms of kind of capturing the entry and then, you know, looking at the schedule, I never felt I've got kind of chunks of information which I've captured here that I haven't got a category to put them against"* (OT3C1.4).

Getting the logs completed accurately required practice and some occupational therapists reported that they wished that they had practiced using them more

before the study had begun. Completing the logs *enhanced practice and clinical note writing* and it supported occupational therapists reflective practice to think more about what they were writing. One occupational therapist reported that *"it was almost like a template for writing the entry"* (OT4C1.13). A *future consideration* was suggested, which was to consider how what the participants progress with their goals in-between sessions could be captured?

Sub-category	General category	Main category
Recruitment challenges	*Recruitment and enrolment*	*Doing occupational therapy research in practice*
Recruitment needs to be 'quick and slick'		
Making enrolment even more successful		
Being a research assistant who happens to be an occupational therapist		
Straight forward, structured and logical	*Utility of the occupational therapy log*	
Takes additional more time to complete		
Identified and captured what actually delivered		
Getting the logs completed accurately		
Enhanced practice and clinical note writing		
Future considerations		
Highlighted what I was doing	*Occupational therapy log revealed the intricacies of occupational therapy practice*	
Insights about the occupational therapy pathway through supervision		
Intervention – starts and ends where it should		
Themes running through each stage of the intervention		
Aspects of occupational therapy pathway carried out in parallel		

Table 6.8a Focus group main category: Doing occupational therapy research in practice

Occupational therapy log revealed the intricacies of occupational therapy practice

Occupational therapists reported that the log highlighted what they were doing and articulated the thinking processes behind what felt like intuition. Further insights about the occupational therapy pathway were gained through professional supervision. It was recognised that the *intervention - starts and ends where it should* and that there were *themes running through each stage of the intervention.* Described by one occupational therapist as:

> "*It broadly starts off where it should do, and it definitely ends when it needs to, but in the middle then there's lots of to-ing and fro-ing and going back to the beginning and doing a bit more of an assessment… which is what happens you know in real life"* (OT4C2.5).

However it was also discussed that, *aspects of the occupational therapy pathway were carried out in parallel* and that the process was non-linear, as life is not linear. Comments related to this included:

- *"More parts of the schedule were happening than I originally thought"* (OT1C1.1).
- *"You almost follow the whole occupational therapy process in one session"* (OT2C2.17).

Table 6.8b describes a further three general categories that formed part of the main category of *doing occupational therapy research in practice*, these were: *outcome measurement, rating adherence* and *balancing research and practice.*

Outcome measurement

There were some challenges with getting the post-intervention outcome measures completed with participants and it was suggested that incentives for participants may help to improve this response. One occupational therapist reported that scoring goals with the

"guy I was working with was very, you know, the whole idea of putting a number onto something was quite alien to him" (OT2C1.6).

Sub-category	General category	Main category
Completing outcome measures	*Outcome measurement*	*Doing occupational therapy research in practice*
Scoring goals alien to some service users		
Motivation and engagement are different things	*Rating adherence*	
Two adherence ratings easier and clearer		
Adherence reflective of client groups engagement on caseload		
Balancing managing caseload and picking people up for study	*Balancing research and practice*	
Optimum length of intervention		
Being care co-ordinator drawn into other elements		
Time constraints can make detailed write ups difficult		
Peer supervision		

Table 6.8b Focus group main category: Doing occupational therapy research in practice

Rating adherence

It was articulated that *motivation and engagement are two different things.* It was questioned:

"Should it be more around motivation to engage then rather than engagement?" (OT1C2.9).

This was expanded upon, in relation to appreciating that other factors can prevent a person from doing what they set out to do, even when they are motivated. It was suggested that two adherence ratings would be easier and clearer, that is one for the actual occupational therapy session and another rating for activities carried out as planned, in-between the one to one

occupational therapy sessions. One occupational therapist reflected on the adherence levels achieved:

"I think the adherence that we're talking about is probably reflective of the client group that we are working with" (OT2C2.14).

Balancing research and practice

This last general category was related to balancing occupational therapy research with practice. Occupational therapists spoke of the challenges of *balancing managing a caseload and picking up people for the study.* These challenges included time being a limiter when they already had a full caseload and it was suggested that staggering recruitment would help this. Additionally it was suggested that it would be more realistic to pick up six service users for the study over a six month period. The *optimum length of the intervention* was discussed, some occupational therapists raised concerns that the six month time limit may have negatively impacted on the overall outcomes for the study; whilst it was also recognised that for some participants six months of occupational therapy is ample.

One occupational therapist was also the care co-ordinator for the participant that they were providing occupational therapy for. It was identified that *being a care co-ordinator can draw you into other elements* and can sometimes be confusing to *wear more than one hat*. Additional time to write up interventions sessions was suggested because *time constraints can make detailed write ups difficult.* Finally *peer supervision* was reported as a useful mechanism to learn from each other and provided extra support about being involved in the study.

6.5 Utility of the outcome measures

The actual outcome measure scores from the study were reported in Section 5.2.6. The data in this section relates to the utility of the outcome measures both in the time they took to complete, which is presented in Table 6.9. Also critically the participants experience of completing the outcome measures; Table 6.10 shows how participants rated the time they took to complete and the rating of the relevance of the questions are shown in Table 6.11.

The completion of outcome measures with participants was timed. Table 6.9 shows the time taken for carrying out the baseline and post-intervention outcome measures. Two sets of baseline outcome measures were not timed and therefore no data is available. Post-intervention outcome data was available for 14 participants. The table shows that all post-intervention outcome measures were completed quicker than the baseline assessment. The Time Use Survey took the longest to complete taking the mean was 22.47 minutes, with the SF-36 taking slightly less time on average at 18.91 minutes.

	Time taken to complete outcome measures in minutes (mean)			
	Time Use survey	**SF-36**	**USER-P**	**P-Scale**
Baseline (n=18)	22.78	20.39	13.39	11.28
Post-intervention (n=14)	21	17	10.07	8.64
Baseline + post-intervention (n=32)	22.47	18.91	11.94	10.13

Table 6.9 Time taken to complete outcome measures

The outcome measure completed in the shortest amount of time on average was the P-Scale, which had a mean score of 10.13 minutes and the USER-P took only slightly longer at 11.94 minutes. Participant's experience of the assessment/ outcome measures (time they took to complete) is reported in Illustration 6.3.

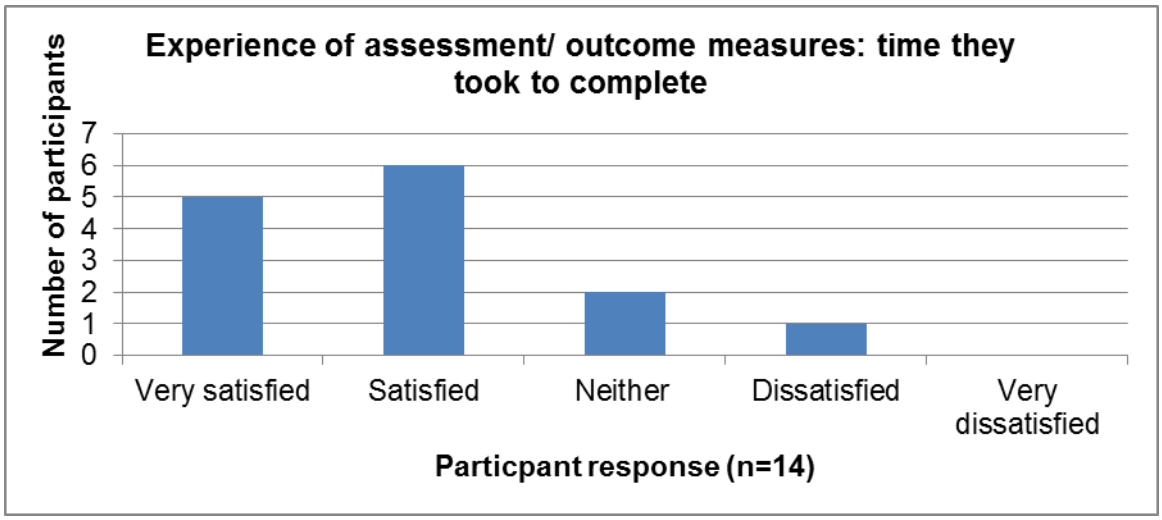

Illustration 6.3 Participant responses: Experience of assessment/ outcome measures (time they took to complete)

Eleven participants (79%) reported that they were either very satisfied (n=5, 36%) or satisfied (n=6, 43%) with the time that the outcome measures took to complete. One participant was dissatisfied with the completion time and two participants (14%) were neither, satisfied or dissatisfied.

With regards to participants experience of the relevance of the questions (see Illustration 6.4), the highest response rate (n=6, 43%) was that participants were neither, satisfied or dissatisfied. Whilst a further six participants (43%) were satisfied (n=3, 21%) or very satisfied (n=3, 21%) and two participants (14%) made up the lowest response which was dissatisfaction with the experience of the relevance of the questions.

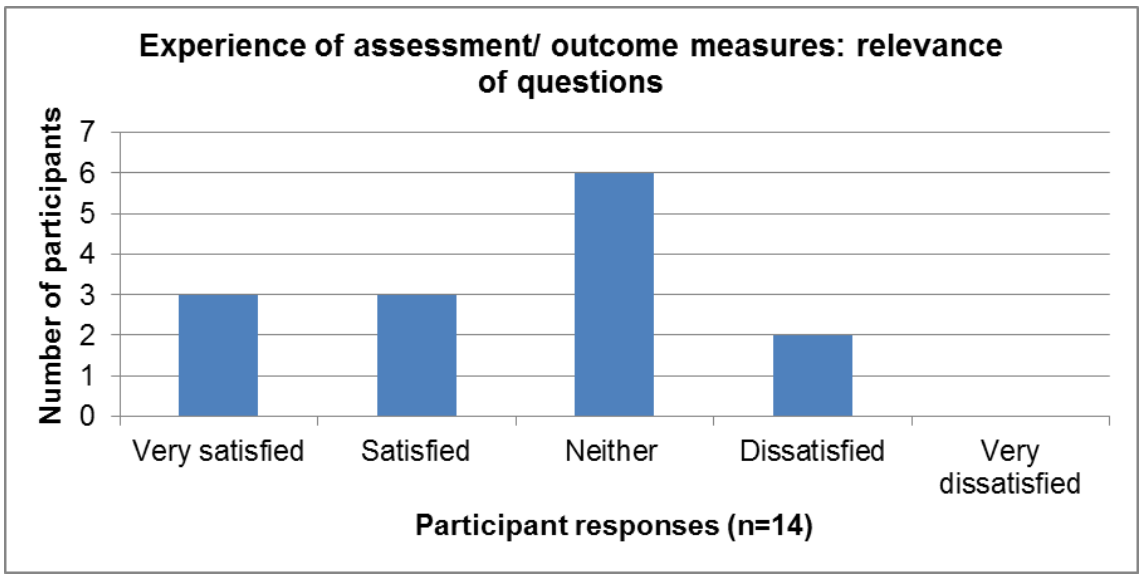

Illustration 6.4 Participant responses: Experience of assessment/ outcome measures (relevance of questions)

6.6 Summary

This chapter has brought together the findings related to the process outcomes of the study, these were largely qualitative findings and the majority were generated from the two focus groups with the occupational therapists. In relation to the study objective of understanding more about how occupational therapy enables people with a diagnosis of psychosis to participate in activities of everyday life, three main categories emerged through the content analysis (see Section 6.3). These categories were: every time a person-centred contact, occupational needs formulation was the focal point and enablement to do more, be active and be more and were triangulated with data from the participants about their experiences of their occupational therapists. Sections 6.3.4 and 6.3.5 summarised and brought together the enablers and barriers to participation in activities of daily living and the ultimate success of occupational therapy from the perspective of the participants and the occupational therapists. These finding will be discussed in the context of the study outcomes and also in relation to the established literature in this area in Chapter seven.

The fourth main category that emerged from the focus groups analysis was: doing occupational therapy research in practice (see Section 6.4). This highlighted a number of process aspects of the study which were successful and those areas where the research process could be even more successful. The utility of the occupational therapy log and how it revealed the intricacies of occupational therapy practice, was revealed in more detail. This also contributed to the understanding of its validity as a description of occupational therapy for practice and research purposes. These findings will be brought together and discussed with the *TIDieR* (Hoffmann et al 2014) information about what was actually provided in the discussion; Chapter seven, next. The qualitative findings regarding the utility of the method to measure fidelity and adherence will also be discussed in the next chapter together with the outcome data that was generated through using the processes outlined to measure these. The findings related to the utility of the study outcome measures (see Section 6.5) were triangulated in this chapter from the participant's perspective and the occupational therapists perspective and with the quantitative information about how long the measures took to complete. A discussion regarding the method of measuring participation will be carried out in the next chapter, in the context of the study participant population and numbers recruited.

Chapter 7 Discussion

7.1 Introduction

This chapter discusses the findings from the feasibility study predominantly, and also including the development and evaluation of the intervention specification (development presented in Chapter 4). It then considers the results in the context of the evidence base at the beginning of this thesis. It discusses how the key uncertainties (see Section 3.1.3) in the design of a pragmatic RCT of occupational therapy with people with a diagnosis of psychosis, living in the community have been explored within this thesis. This includes how these findings have contributed to extending the occupational therapy knowledge base in this area of practice and research. The chapter concludes with recommendations for the next steps required to conduct a large pragmatic RCT (see Section 7.12).

The discussion interprets the study outcomes (see Section 7.2), and considers what these indicate with regards to effectiveness. The study sample is then considered (see Section 7.3), including how indicative this is of occupational and participation needs of people with a diagnosis of psychosis (see Section 1.2). It explores how the characteristics of those who completed therapy differed from those who withdrew; including how this may relate to NICE guidelines (2014b, c) and the implications for a future pragmatic RCT study. Recruitment within the feasibility study is discussed (see Section 7.3.2); recommendations are made for improved processes in a future pragmatic RCT study. The outcome measures and processes of measuring participation in activities of daily living are critiqued; implications and recommendations for future research are drawn out (see Section 7.4). The results of the occupational therapy

intervention provided and the validity of the description of occupational therapy are also discussed (see Section 7.5); including the utility of the occupational therapy intervention log for this study and for future practice and research. The findings regarding the method for monitoring and measuring fidelity are deliberated (see Section 7.6), and the method for measuring adherence is also reviewed (see Section 7.7). The findings about how occupational therapy enables participation in activities of daily living are discussed (see Section 7.8).

The limitations of the study and implications of these are drawn together in (see Section 7.9) and the challenges and lessons learned are discussed in Section 7.10. An overview of how the thesis was conceptualised, designed and implemented is given, including a reflection on the contribution to new occupational therapy research and practice knowledge (see Section 7.11). The thesis is drawn to a close and outlines how this thesis has set the foundations for an occupational therapy pragmatic RCT with people with a diagnosis of psychosis living in the community and recommendations for future research (see Section 7.12).

7.2 Study outcomes

This section interprets the study's outcomes from the feasibility study results (see Section 5.2.6). The outcome data was collected to measure participation in activities of everyday life, self-reported experience of occupational performance and satisfaction with occupational performance and health-related quality of life (see Section 3.4.4.1). These were the occupational therapy outcomes that were identified as part of developing the intervention specification and were consistent with the hypotheses for the thesis (see Section 4.4.2). Specific attention was given to identifying and measuring these outcomes for the study

because outcomes were sparsely reported on in the effectiveness studies identified in the systematic review (see Section 2.4.5.2). Also part of the study was about exploring a valid and reliable method of measuring participation in activities of everyday life; this is focussed on later in this chapter (see Section 7.4)

The findings from each of the outcomes measured at baseline and post-intervention, for the 14 participants who provided full outcome measure data sets, are discussed. The ratings of occupational therapy effectiveness from the participants (see Section 7.2.1.3) and occupational therapists (see Section 7.2.1.6) are also discussed. Unfortunately the size of the final sample was much lower than planned (see Section 3.5); this affected the ability to generalise the results to the wider population (the sample size, characteristics of the participants and recruitment rates are discussed in more depth in Section 7.3). It was assumed that the data generated would not have a normal distribution due to it being under the threshold of 30 participants (Bowling 2009). Given this scenario the Wilcoxon signed rank test was utilised (as discussed in the methodology see Section 3.8.2). The plan was also to compare the results between the two centres but this was also not possible due to the sample size; therefore the data from both of the centres was collated and analysed as one group.

7.2.1 Indication of effect

Feasibility studies are generally not expected to have sample sizes large enough to adequately power statistical null hypothesis testing (Tickle-Degen 2013). As this was a feasibility study the results give a potential indication of effect. The primary and secondary outcome measure results were presented as

descriptive statistics with calculated effect sizes in Section 5.2.6. Whilst also recognising that due to the size of the sample it was not possible to generalise the findings to the wider population, outside of the participants involved in the study (i.e. the study had internal rather than external validity).

7.2.1.2 Time use

The primary outcome was time use; the baseline and post-intervention scores of constructive economic activity and structured activity both showed increased scores; however neither achieved statistical significance *(p>.05)* (see Section 5.2.6.1). More time was spent in structured activity than constructive economic activity at baseline and post-intervention; a phenomenon that was also found in the results of the study by Fowler et al (2009), who measured time use in a study of cognitive behavioural therapy for improving social recovery in psychosis. Frequency in participation was measured by the USER-P; however, whilst it showed a positive change score for vocational activity, it differed from the time use results with regards to frequency of participation in leisure and social activity; which saw a reduction in the change score. Neither of the USER-P scores were found to be statistically significant *(p>.05).* Edgelow and Krupa (2011) also measured time use in a pilot study of an occupational time-use intervention for people with a diagnosis of psychosis. Participants in the occupational therapy group spent more time in activity per day than the control group; however this was not found to be statistically significant (Edgelow and Krupa 2011).

7.2.1.3 Participants ratings of effectiveness

Whilst the positive changes in the time use scores did not reach a level of statistical significance, information from participants about their experience of occupational therapy did show that the majority of those receiving therapy found

it to be effective, at enabling them to improve their participation in activities of daily living meaningful to them. Participants rated their experience of effectiveness through the participant questionnaire completed with them by the research assistants, who were independent of the researcher and the occupational therapists providing the therapy (see Appendix 14). This showed that the majority of participants (n=10, 71%) either strongly agreed or agreed that their occupational therapist made it possible for them to participate in more activities and occupations that were meaningful to them. Furthermore, the same percentage of participants also reported that they either strongly agreed or agreed that they were more satisfied with their participation in the activities of daily life most meaningful to them which suggests the changes in time use scores had personal meaning to the participants.

7.2.1.4 Self-reported experience of occupational performance and satisfaction with occupational performance

Self-reported experience of occupational performance *(p=.002)* and satisfaction with occupational performance *(p=.001)* results indicated that the positive changes achieved were clinically significant and statistically significant *(p<.05).* It could be argued that this scoring involved bias in favour of occupational therapy because the occupational therapists, rather than the research assistants, completed these with the participants. However, in a study carried out by Sturkenboom et al (2012), the COPM was used as the primary outcome measure for an occupational therapy intervention, with people with a diagnosis of Parkinson's disease. These were completed by assessors independent of the therapists and the measure was found to be sensitive enough to detect statistically significant change. Satisfaction with participation was also measured by the USER-P in this study; the post-intervention scores also

showed a positive change reflecting the change indicated in the COPM scores. Although this was not found to be statistically significant, it may be that the small sample size impacted on the outcome of the effect calculation (i.e. it is a type II error).

7.2.1.5 Participation

The results for participation restriction showed that the change scores indicated a reduction in restriction on both the USER-P and the P-Scale; however these were not shown to be statistically significant *(p>.05).* Even so, it is interesting that both of the scores from different measures showed positive change. This suggests that this may be an outcome that occupational therapy can have a positive effect on. However, as this was not statistically significant on either measure, it cannot be deduced that this occurred other than by chance. It is important to recognise that the potential impact of a small sample (i.e. underpowered) on the outcome of the statistical analysis in terms of a possible type II error.

7.2.1.6 Occupational therapists rating of effectiveness

The occupational therapists gave an average rating score of 6.5 (scale 0-10, 0=not successful to 10=very successful) regarding the effectiveness of the occupational therapy intervention at improving participants' participation in their activities of everyday life. Some of the reasons behind this rating score are discussed further in Section 7.8).

7.2.1.7 Health-related quality-of-life

Health-related quality-of-life/ quality of life, was not measured by either of the individualised client-centred, occupational therapy intervention effectiveness

studies (i.e. Cook et al 2009, Edgelow and Krupa 2011) identified in the systematic review (see Table 5.10). In this study self-evaluated transition (SET) which rates the amount of change the participants have experienced in their health in general increased from baseline to post-intervention and this change was found to be statistically significant *(p=.026) (p<.05).* Despite the sample size this provides some support for the belief that occupational therapy is associated with health (see Section 1.3.3), as articulated in the hypothesis (see Section 3.4.3) and applicable for this study sample.

The results from the SF-36 were mixed across the eight health domains. Four health domains showed improvements from the baseline to post-intervention scores; with bodily pain being statistically significant *(p=0.46) (p<.05).* The other four health domain scores indicated that health burden had increased; none of these changes were found to be statistically significant *(p>.05).* A limitation was that the health-related quality of life data was presented as mean scores and compared against the means for the US general population. This data was used because there was no norm specific data related to having a diagnosis of psychosis in the UK (Maruish 2011).

This was a small sample and there was with-in group variability, as would be expected with a smaller sample size. However the findings are promising, the results have shown positive change scores from baseline to post-intervention on: time use, self-reported experience of occupational performance and occupational performance satisfaction, satisfaction with participation, and participation restriction. In addition the self-reported experience of occupational performance, and occupational performance satisfaction outcomes were found to be statistically significant for the participants in this study *(p<.05).* Participants were also found to have experienced better health in general (SET) at post-

intervention and this change was also found to be statistically significant *(p<.05).* As this was a before-after feasibility study, no follow-up outcome assessment was carried out. It is important that this is incorporated into the next stage of testing the effectiveness of this occupational therapy intervention.

7.3 Study sample

The aim was to recruit a study sample size of 64 participants, to allow for a drop-out rate of approximately 6%; this aimed to achieve a final sample size of sixty; thirty from each centre (see Section 3.5). This followed the recommendation that the target sample size for a pilot study should be 30 participants in each intervention arm (Lancaster et al 2001).

7.3.1 Recruitment

Of the 36 service users identified as potentially eligible, twenty participants were recruited into the study, which is approximately 56% of those initially identified. Some of the circumstances which prevented participants from being recruited reflected their level of health and well-being: three (18.75%) individuals were admitted to hospital, one (6.25%) individual was physically too unwell and two (12.5%) individuals were unable to give informed consent. There was a noticeable number of potential participants (n=5, 31.35%) who gave verbal consent to be part of the study and when contacted by the research assistants they withdrew verbal consent. This phenomenon was discussed in the focus group conversations (see Section 6.4). At one of the centres there was a time delay between the participants giving verbal consent, to them then, being contacted by the research assistants. It was identified that specifying timescales on the enrolment process would address this discrepancy in future studies, and may improve recruitment rates overall. In addition to the learning from the actual

recruitment process designed, part of the conversation in the occupational therapists focus groups was that more time was needed to recruit the target sample size, due to already having an existing occupational therapy caseload (see Section 6.4).

Twenty participants commenced occupational therapy and four participants withdrew during therapy; occupational therapy was completed with 16 (80%) of the 20 participants recruited. This represents an 80% retention rate, which is at the threshold for an acceptable sample size when scoring the methodological quality of an effectiveness study, with short-term follow up (Steultjens et al 2002). However this is a smaller retention rate than that found in other studies with participants with a diagnosis of psychosis (Fowler et al 2009, Cook et al 2009).

Two participants were lost to follow up for the post-intervention outcome measures and the reasons reported were that they did not want to repeat the post-intervention outcome measures. However one of the participants did complete the COPM as part of the occupational therapy session. This reason for participants being lost to follow-up is concerning regarding the utility of the outcome measure process; the potential burden it can put on the participants and will be discussed further in Section 7.4.5.

The recruitment process for this study has generated data to contribute to a power calculation of an appropriate sample size for a larger pragmatic RCT in the future. It has identified some process areas for development regarding timescales required to complete the enrolment process.

7.3.2 Characteristics of participants

The characteristics of those participants who completed and withdrew from occupational therapy were compared using descriptive statistics. The largest variations were with regards to the amount of time use in constructive economic activity and structured activity, with the group of participants who withdrew showing the lowest amount of time spent in both categories of activities. This suggests the intervention schedule may need to include engaging service users with low volition.

The other noticeable difference was with regards to the type of diagnosis of psychosis. The majority of those who withdrew had a diagnosis of affective psychosis (e.g. bipolar disorder), compared to the majority of those who completed therapy who had a diagnosis of non-affective psychosis. The reason for this is not known. However the needs of having a different type of diagnosis of psychosis has been recognised as requiring different type of interventions (NICE 2014b,c) as there is now separate guidance for the two different diagnosis categories of psychosis. This will need to be monitored in future studies.

There was only one participant out of all of those recruited who was in employment; this reflects some of the associated impacts of having a diagnosis of psychosis (see Section 1.2.2). All of the participants who were recruited into the study had a problem with their activities of daily living as indicated by the HoNOS scores (see Table 5.2). This was incorporated as part of the inclusion criteria for this study, following the learning from critiquing occupational therapy effectiveness studies using the *TIDieR checklist* (Hoffmann et al 2014) in the systematic review (see Section 2.4.3). The systematic review found that only

four studies, out of 18, stipulated some kind of occupational need/ problem with activities of daily living.

7.4 Outcome measurement

An objective of this thesis was to explore and develop a valid and reliable method, with good utility, for measuring participation in everyday life, for a pragmatic RCT. This objective was defined following the outcome of the systematic review (see Section 2.6). It revealed that in the occupational therapy effectiveness studies reviewed approximately half of all, of the outcome measures used, were relevant to the outcomes of the review (see Section 2.4.3). The majority measured occupational performance in some format. There was no consensus about which outcome measure to use. Of the relevant 26 outcome measures, these were mostly used in only one study each; the Global Assessment Scale (GAS) (Hayes et al 1991, Liberman et al 1998) and the Social Functioning Scale (SFS) (Cook et al 2009, Mairs and Bradshaw 2004) were each used twice. When reviewing the evidence for individualised client-centred occupational therapy interventions, both of the included studies measured participation and satisfaction with activities of everyday life. However both studies measured these differently; Cook et al (2009) measured these via engagement in employment related activity and Edgelow and Krupa (2011) via the Profile of Occupational Engagement for People with Schizophrenia (POES).

The occupational therapy outcomes stated in the hypotheses (see Section 3.4.3) needed to be matched with valid and reliable outcome measures to measure them. The challenge with this was that there was no consensus on the most appropriate measure of participation for use in mental health (see Section 1.3.4). Furthermore there was an issue with the concept of ‘participation’ in the way that it is presented in the *ICF* (WHO 2001); it has not been well defined and

conceptual clarity was lacking (Khetani and Coster 2007). The participation outcome measures used in this study were selected based on a separate piece of work to this thesis, to define participation and map the content of these measures against the definition (see Section 3.4.4.2.1). This identified that there was not strong validity and reliability testing on the two measures that had the greatest face validity (i.e. the P-Scale and USER-P). The planned method to measure participation in this feasibility study built on that work by utilising these participation measures.

The aim was to test the concurrent criterion validity of the participation measures by using an established measure, of a construct of participation; this was time use and the adapted version of the TUS (Short 2006) (see Section 3.8.3). However, the feasibility study did not achieve the target sample size; the sample size was too small to enable any meaningful statistical analysis of correlation. Despite this it was possible to compare the direction of change from the mean outcome measure scores, to see how these related to each other on the face of it.

A summary of the direction of change (baseline to post-intervention) of the outcome scores of participation and some of the constructs of participation are given in Table 7.1. This shows that the majority of the mean time use scores, increased from baseline to post-intervention. Additionally both of aspects of time use were shown to have positive change as measured by the adapted TUS, which was the primary outcome measure. Table 7.1 also shows that the mean scores for participation restriction reduced as derived from both the P-Scale and the USER-P. The mean scores for satisfaction with participation increased from both the USER-P and the COPM. It is important to note that it was only the

COPM that was found to be statistically significant. However the results from the comparison are promising and suggest they would benefit from statistical analysis of the correlations, with a larger sample size.

Construct of participation	Specific description of participation or construct of participation, (outcome measure) and ***direction of change of mean outcome measures scores (baseline to post-intervention)***	
Time Use	Constructive economic activity (TU Survey) ***Increased***	Frequency vocational activity (USER-P) ***Increased***
	Structured activity (TU survey) ***Increased***	Frequency social & leisure activities (USER-P) ***Reduced***
Participation restriction	Participation restriction (P-Scale) ***Reduced***	Participation restriction (USER-P) ***Reduced***
Satisfaction with participation	Satisfaction with participation (USER-P) ***Increased***	Satisfaction with occupational performance (COPM) ***Increased***

Table 7.1 A summary of the direction of change (baseline to post-intervention) of participation & constructs of participation outcome scores

7.4.1 Measuring time use

There was an anomaly in the scores of time use shown in Table 7.1, that is, the direction of change for the mean structured activity score, measured by the adapted TUS shows an increase by contrast the USER-P shows a decrease in the frequency of social and leisure activities. The reason for this is unclear; it may be related to how the different measures generate the information about the actual time used. The adapted TUS gives the freedom for the participant to define their own time use in hours, whereas the USER-P asks participants to select time use using a range (e.g. 1-8 hours). It may therefore be that the TUS is more sensitive to capturing actual time use?

This study found that the adapted TUS took the longest time to complete of all the outcome measures used in the study, which was on average 22.47 minutes; putting the greatest burden on participants. There were no issues, with the utility of the adapted TUS for participants that were reported on specifically in the study by Fowler et al (2009). The exact adapted TUS (Short 2006) from Fowler et al (2009) was not accessible and therefore similar adaptions were made to the TUS (Short 2006) as described in the study. However these may not have been exactly the same as those made by Fowler et al (2009).

Time use has been shown to have positive changes in the mean scores for participants in the study and although these were not statistically significant, it does warrant further investigation as a primary outcome measure. There are examples of time use measures being developed in occupational therapy (Berjerholm et al 2006). One of the next steps towards running a pragmatic RCT would include reviewing other time use measures in more depth, perhaps by carrying out a systematic review. This would enable an even more robust evaluation of the most valid and reliable measure, with good utility for people with a diagnosis of psychosis.

7.4.2 Measures of participation

Both the USER-P and the P-Scale were found to be sensitive enough to detect change in participation restriction and satisfaction with participation (see Section 7.2.1.5). They were also shown to have minimal participant burden, with the average times to complete the USER-P and the P-Scale being 11.94 minutes and 10.13 minutes respectively.

7.4.3 Self-reported experience of occupational performance and satisfaction with occupational performance

Self-reported experience of occupational performance and satisfaction with occupational performance was measured using the COPM. This was shown to be sensitive enough to detect change, which was then found to be both clinically and statistically significant (see Section 7.2.1.4). This supported the findings from Cresswell and Rugg (2003); the COPM was used with nine clients with a diagnosis of schizophrenia, receiving community-based occupational and the outcomes showed clinically significant improvements.

7.4.4 Measuring health-related quality of life

The SF-36 was used to measure health-related quality of life (see Section 3.4.4.2.4). In this study it took on average 18.91 minutes to complete with participants, which was the second longest length on time and needs to be considered in planning future studies because of the related participant burden. When analysing the outcome measure data it became apparent that there was no norm-based scores for people with a diagnosis of psychosis in the UK and therefore the norms for the United States general population were utilised when transforming the data (see Section 5.2.6.2). This may have affected the validity of the final analysis as it was not diagnosis specific. In terms of next steps regarding a measure for health-related quality of life this needs to be explored to include more diagnosis specific considerations.

7.4.5 Utility of the method used for outcome measurement

The results from the feasibility showed that the majority of participants were either satisfied or very satisfied (n=11, 79%) with the time taken to complete the outcome measures (see Illustration 6.3). Participants were asked about the

relevance of the questions asked and this generated a mixed response, with six (43%) participants reporting that they were neither, satisfied or dissatisfied with this (see Illustration 6.4). It would be beneficial to do some more exploration in this area, as the repetition of the outcome measures was also a reason given for two participants being lost to follow up (see Section 7.3.1). Further collaboration and consultation with service users and carers would be beneficial in the design of future studies.

7.5 Occupational therapy description; intervention specification

One of the objectives of the thesis that emerged was the need to create a valid description of occupational therapy that had good utility for RCT purposes. The systematic review used the *TIDieR checklist* (Hoffmann et al 2014) to guide the extraction of data, which was used to describe the occupational therapy interventions in the studies. It was found that the descriptions of occupational therapy did not allow for full replication. On further investigation there was no occupational therapy intervention specification for individualised client-centred occupational therapy that had been shown to have good utility for RCTs for people with a diagnosis of psychosis. Subsequently the first part of the method for this thesis was to develop an occupational therapy intervention specification for use in RCTs. This process was structured using the *Developing and Evaluating Complex Interventions guidelines* (MRC). It was then reported using the Criteria for reporting the development and evaluation of complex interventions in healthcare (*CReDECI)* (Mohler 2012) in Chapter four. Developing and evaluating complex interventions has been referred to as:

‘unravelling the black box’ (Sermeus 2015, p.112).

The occupational therapy intervention specification developed (see Appendix 13, p.364) was evaluated as having face validity by a number of different stakeholders (see Section 4.4.3.1, Step 4). The validity of this was then tested further by utilising it within the feasibility study.

7.5.1 Satisfying the requirements of the *template for intervention description and replication (TIDieR) checklist* (Hoffmann et al 2014)

All of the items in the *TIDieR checklist* (Hoffmann et al 2014) were captured and reported on through the processes embedded within the feasibility study. These are reported in full in Section 5.2.3. The implications about what was provided will be discussed later in this chapter (see Section 7.8). Fidelity (see Section 7.6) and adherence to occupational therapy (see Section 7.7) are also discussed. This level of reporting regarding what was provided as occupational therapy in this feasibility study is, in contrast to the majority of the descriptions of occupational therapy effectiveness studies in the systematic review (see Section 2.6) was very detailed. It was critical to achieve this to ensure that a future pragmatic RCT would be assessed as having high methodological quality (Steultjens et al 2002). This is important with regards to the rigor of research and the conclusions that can subsequently be drawn. A robust pragmatic RCT is more likely to be included in systematic reviews, and so contribute to the overall body of evidence in this area of occupational therapy research.

7.5.2 Valid description of occupational therapy

As already highlighted the intervention specification (summarised in Appendix 13, p.364) was found to have face validity with stakeholders. Its validity was strengthened in the feasibility study; the occupational therapists could use it to work with the participants to deliver the occupational therapy. The occupational

therapists recorded the sessions using the *Occupational therapy intervention log* (see Appendix 13, p.399) after they had seen the participants. There was also the opportunity to record occupational therapy that was provided and not described by the intervention specification. The results showed that the intervention specification captured on 98% (i.e. 184 of 188 occasions) the occasions when occupational therapy interventions carried out) (see Section 5.2.3.8). This shows that the description of occupational therapy is valid; it describes occupational therapy practice, and has the utility within research effectiveness studies.

The approach used in this feasibility study to develop and evaluate the occupational therapy intervention differed from how the Cook and Birrell (2007) developed their occupational therapy intervention schedule. They used a Dephi study method to develop and test the validity of the schedule. The intervention schedule was also used differently in the pilot study. It was completed retrospectively by assessors reviewing the case-notes to check out what had been done. It was not completed by the therapist carrying out the therapy. Whilst a landmark in its time, the Cook and Birrell (2007) intervention schedule had too broad a scope to enable it to have the utility required for a RCT.

The occupational therapy intervention specification developed and utilised in this thesis also connects occupational therapy theory, with practice and occupational therapy outcomes (see Appendix 13, p.364). This was achieved by applying the task analysis approach as described by Giltlin (2013). It also differs from the occupational therapy descriptions identified by the systematic review (see Table 2.9), where the theory was not always completely explicit and the outcomes did not always obviously connect to occupational therapy theory.

Subsequently the hypotheses generated for the feasibility study reflected the intervention specification. As this was a feasibility study null hypothesis testing was not carried it. However, it does lay the foundation for the next phase in the development of an occupational therapy pragmatic RCT, where the hypothesis of this relationship between occupational therapy and health can be tested under research conditions as recommended by Creek and Hughes (2008).

7.5.3 Utility of the occupational therapy intervention specification and log

Use of the *occupational therapy intervention log* (see Appendix 13, p.399) enabled comprehensive recording about what occupational therapy was provided and it satisfied the requirements outlined in the *TIDieR checklist* (Hoffmann et al 2014). The majority of the logs were submitted as completed in full, which could be taken as an indicator of utility. The occupational therapists discussed the *occupational therapy intervention log* in the focus groups. These were captured within the main category of doing occupational therapy research in practice (see Section 6.4). One of the general categories was related to the utility of the *occupational therapy intervention log;* it was discussed as being straight forward, structured and logical and it identified and captured what was actually delivered. However it was also acknowledged that it did take more time to complete. The second general category in the analysis of focus group data was: Occupational therapy log revealed the intricacies of occupational therapy practice. One occupational therapist described it as *the thinking behind the occupational therapy intuition.*

Occupational therapists spoke of it highlighting what they were doing during their occupational therapy sessions and that using it in supervision had brought further insights about their practice. These conversations are clear illustrations that the intervention specification is a valid description of occupational therapy.

7.6 Fidelity

There were two critical aspects with regards to fidelity in the feasibility study, that is (a) the monitoring and supporting of fidelity throughout the study (7.6.1) and (b) the method of measuring the fidelity of the occupational therapy provided in the study (see Section 7.6.2). The actual levels of fidelity and adherence are discussed in Section 7.8.

7.6.1 Fidelity monitoring

It is thought that if fidelity is monitored throughout, it improves the overall fidelity provided. The processes used to monitor fidelity were reported in Section 5.2.3.9. As the study did not report any concerns with regards to fidelity it can be surmised that this monitoring was a supportive approach.

7.6.2 Measurement of fidelity

Fidelity was sparsely reported in the studies identified in the systematic review (see Section 2.4.4), with only 14% of the included studies reporting their methods of measuring it and fidelity levels. Fidelity to the occupational therapy intervention as described in the intervention specification was reported and assessed in depth (see Section 5.2.3). This was because this was a feasibility study and it was also developing and evaluating occupational therapy as a complex intervention. The need to report on the processes in feasibility studies has been advocated to be as important as reporting on full trials with regards to developing and evaluating complex interventions (MRC 2008).

The standard in this study was that all objectives in the intervention specification needed to be completed to have fidelity to the occupational therapy intervention (see Table 4.5). This was devised based on learning from the Cook et al (2009) study. In that study contamination between groups was found where the control

group was reported to have potentially received occupational therapy. This is because there was some evidence of the components of the interventions schedule being provided to the control group; the true extent and the details were not given. It would seem apparent that one component of an intervention schedule being provided would not constitute occupational therapy; however this was not stipulated as a condition to measuring fidelity.

There does not seem to be a consensus on what is an acceptable level of fidelity expected in an effectiveness trial. This study achieved an overall fidelity level of 77% which was close to the level performed (74%) in the randomised controlled feasibility study (Sturkenboom et al 2012), which was deemed to be of an acceptable level.

Through reviewing the results regarding the levels of fidelity of each of the occupational therapy objectives an anomaly became apparent. That was that both objective five; implementing occupational therapy interventions (see Section 5.2.3.1.5) and objective eight; discharge from occupational therapy (see Section 5.2.3.18) could be appropriately achieved without carrying out all of the key activities. For example: if a participant's needs were reviewed at six months and they had continued needs, they would not be discharged therefore that key activity would appropriately not be carried out. This requires some more consideration to support full reporting on fidelity levels.

7.7 Adherence

Adherence to treatment was reported in only 22 percent of the studies included in the systematic review (see Section 2.4.4). Out of the individualised client-centred occupational therapy studies, adherence was only measured by Cook

et al (2009). Adherence to the intervention schedule was audited through the participant's notes.

The data regarding adherence in this study was triangulated to support the validity of the findings. These came from both the participants and the occupational therapists (see Illustration 5.15). Interestingly the scoring was relatively closely scored by the occupational therapists and participants. There were some issues with regards to reporting from participants, as two were lost to follow up and one participant reported that there was not a plan to adhere to. Participants reported once at the end therapy and the occupational therapists reported after each session. This decision was taken to minimise participant burden with regards to being involved in the study.

The occupational therapists in the focus group conversations, reported some challenges with rating adherence (see Section 6.4). This was with regards to giving one rating that covered adherence during the face to face session and including how much the participant had continued with their occupational therapy as agreed in-between that session and the next. A suggestion was made, that these could be measured and recorded as two separate ratings; making this process easier for the occupational therapists and potentially increasing the accuracy.

The process of measuring adherence in this study was similar to that used by; Sturkenboom et al (2012) in a feasibility study for people with Parkinson's disease. It also proved to be an acceptable method of measuring adherence within this study, with only a minor adjustment being required.

7.8 How occupational therapy enables participation in activities of everyday life

It is important to reflect on the feedback from participants who were part of the study and the majority (n=10, 71%) agreed or strongly agreed that occupational therapy had made it possible for them to participate more in the activities and occupations meaningful to them.

The reporting systems integrated into the feasibility study method have enabled the associated actual provision of occupational therapy to be explicit regarding this feedback from participants. The reporting of the occupational therapy delivered; was in a manner that was consistent with the *TIDieR checklist* (Hoffmann et al 2014) (Section 5.2.3). The results show that data collection processes of the study were able to fulfil these reporting requirements, which will support the methodological quality assessment of a future pragmatic RCT.

There was variation in the provision of occupational therapy; this was to be expected as individual tailoring was specified in the delivery details (see Table 4.5). Tailoring was also used in the study by Cook et al (2009); however the specific details of this were not specified in the paper; apart from some details regarding the variation in the length of time of the intervention, which was provided for up to 12 months. This shows that this study has advanced the reporting details of occupational therapy in preparation for further effectiveness research; it has addressed many of the reporting issues that were undermining studies in the systematic review (see Section 2.6).

It is interesting that participants identified their barriers to participation largely being related to themselves and their physical and mental health (see Table 6.6). In contrast the occupational therapists identified that the main barriers to

the success of the intervention were: environmental factors, with some participant factors and then service related issues such as breaks in therapy or dual roles such as care co-ordination.

The knowledge about how occupational therapy enables participation has also been illuminated from the conversations in the occupational therapists focus groups. The occupational therapy intervention log was discussed; identifying that it revealed the intricacies of occupational therapy practice (see Section 6.4). It illuminated how the occupational therapy process is both linear and non-linear and sometimes key activities run in parallel during an intervention. The occupational therapy intervention logs were able to demonstrate the extent of this; however that further analysis was outside the scope of this thesis. The use of the occupational need formulation as being a focal point for the occupational therapy interventions was highlighted. Carrying out person-centred contact every-time was described as a way of being; included taking a collaborative process, which was recognised as a catalyst for change (see Section 6.3.1). Enablement to do more, be active and be more was a strong theme from the content analysis of the focus group (see Section 6.3.3). It is interesting to triangulate this theme with the quantitative data about provision of the occupational therapy (see Section 5.2.3.2). This shows that the occupational therapy objective provided the most, was objective five and it focussed on making it possible for participants to participate more in those activities and occupations most important to them.

7.9 Summary of main limitations of study

The limitations of the study have been discussed throughout this chapter; this section brings the main limitations together with the associated implications and recommendations for a pragmatic RCT.

Recruitment

The study recruited less participants (n=20) than planned (n=64), this had implications for this study and the generalisability of the study outcomes (see Section 7.3.1). It was identified that more time was needed to recruit the target sample size, due to the demands from the pre-existing caseloads of the occupational therapists (see Section 6.4). It was suggested that it would be more realistic for each occupational therapist to recruit approximately one new participant to receive occupational therapy in the study a month; occupational therapists were also beginning to work with other new service users whilst taking part in the study.

There was a time delay between some participants giving verbal consent, to them then, being contacted by the research assistants and a number of participants were lost over this period. This could be mitigated against by specifying timescales on the enrolment process.

Measuring fidelity

The method of measuring fidelity was via a self-report method by the occupational therapists providing the occupational therapy. The validity of this was strengthened by triangulating with conversations in professional supervision with the review of the participant's occupational therapy case notes. However further exploration of the use of shadowing of a random sample of occupational therapy sessions may be able to strengthen the method of measuring fidelity further.

Measuring adherence

There were some challenges with rating adherence (see Section 6.4). Occupational therapists rating of adherence rated both their 1:1 therapy session

and included how much the participant had continued with their occupational therapy as agreed in-between that session and the next. A suggestion was made, that these could be measured and recorded as two separate ratings; making this process easier for the occupational therapists and potentially increasing the accuracy.

Participants rated their adherence only once at the end of therapy or the end of the study. This decision was taken to minimise participant burden with regards to being involved in the study, both from an ethical and pragmatic perspective. This may have affected the sensitivity of the measure; further consultation with service users and carers about this would be helpful to inform a future adherence rating approach.

Participants; qualitative data

The study prioritised engagement and minimising burden on participants as guided by the pragmatic perspective and ethical framework; however this approach also has its limitations with regards to the depth of information generated. The rating scales on the participant questionnaire were helpful and did elicit useful information; however qualitative data generated by using an interview would have been useful to particularly further how occupational therapy enables participation.

Outcome measurement method

One of the objectives was to test the concurrent criterion validity of the participation measures by using an established measure, of a construct of participation; this was time use and the adapted version of the TUS (Short 2006) (see Section 3.8.3). However, the feasibility study did not achieve the target sample size; the sample size was too small to enable any meaningful

statistical analysis of correlation. Despite this it was possible to compare the direction of change from the mean outcome measure scores, to see how these related to each other on the face of it. The results from the comparison are promising and suggest that this relationship would benefit from statistical analysis of the correlations, with a larger sample size.

7.10 Challenges and lessons learned; carrying out research in practice

Reflecting on my experiences of conducting the research work for this thesis, there were a number of challenges to carrying out this research in occupational therapy practice and consequently lessons to be learned for the future.

Balancing research and practice

Balancing the ideal research methodology and design with the practicalities of carrying out research in a clinical setting created some tensions. This was particularly with transforming a research design into actually being able to practically run the study in a practice service setting. Lessons learned from this, were the crucial importance of engagement with those who are most likely to facilitate the research in practice, at the research design and development stage.

Systems and processes

The feasibility study was conducted across two centres; both of the NHS organisations had different systems and operational policies for the services that they were providing where participants were recruited from. For the feasibility study to be facilitated successfully in both centres, it involved setting up different systems with the aim of working to the same feasibility study protocol; some of which was realised once the study had commenced. In the

future this could be managed even more effectively by being explicit about how the main study protocol would be specifically carried out in each of the different centres; achieved through with time spent together to work through this prior to the study commencing.

Preparing occupational therapists to be involved in the research

Occupational therapists who were providing therapy reported that a 'lead in' time to become familiar with using the occupational therapy log would have been beneficial. Therefore a recommendation for a pragmatic RCT would be to include this as part of the study's overall timescales.

Research study management and governance

The feasibility study was approached from a pragmatic perspective with the objective of exploring how to do occupational therapy effectiveness research in practice and therefore also aiming to minimise additional demands on clinical staff. The challenge of this was to balance it with the monitoring, managing and governance arrangements for the research. On reflection this is an area for further development, so that stricter processes to monitor and support recruitment are strengthened. Including clear procedures and agreements between the researcher and all involved with regards to roles and responsibilities and how issues are identified and managed.

7.11 Contribution to the occupational therapy practice and research knowledge base

When considering the contribution to occupational therapy practice and research knowledge it is useful to briefly review what the evidence base was for the effectiveness of occupational therapy with people with a diagnosis of psychosis when the thesis was embarked upon. The starting point was that the researcher was working in practice as an occupational therapy professional

lead and the routine collation of standardised occupational therapy outcome measures revealed consistently positive results. Whilst occupational therapists and therapy are well established in CMHTs (RCPsych 2016, DoH 2001, DoH 2002) the diagnosis specific guidelines for psychosis did not refer to occupational therapy. Some of the interventions listed were within the scope of occupational therapy practice (NICE 2014b, c). There had been calls for more effectiveness research in occupational therapy (Lin 2013, Bannigan et al 2008) and occupational therapy in mental health (COT 2006).

The thesis adopted a systematically phased approach towards developing an occupational therapy pragmatic RCT with people, with a diagnosis of psychosis, living in the community. The first step was to establish a more in-depth knowledge about the current evidence base. A protocol for a systematic review was developed and published on PROSPERO (Inman et al 2015) (see Appendix 1). This delineated the parameters for reviewing the evidence base regarding the question of the thesis and included applying a methodological quality assessment to those studies included in the review (Steultjens et al 2001). The systematic review (see Chapter two) was carried out and due to the heterogeneity between studies, a best-evidence synthesis was applied to synthesise the evidence base (Steultjens et al 2002). It found no evidence of effectiveness of individualised client-centred occupational therapy interventions on participation in activities of everyday life. There was also no evidence regarding the quality of life or health-related quality of life as neither of the two studies measured this (see Section 2.4.5.2). The systematic review importantly identified some areas of occupational therapy effectiveness research that needed addressing in this area, these included: the sparse number of effectiveness studies, generally low methodological quality, mostly insufficient

descriptions of occupational therapy that would not enable replication; no consensus on outcome measure/s to use and limited reporting on the measurement of fidelity and adherence to the occupational therapy interventions.

The phased approach of the thesis was guided by the application of the *Developing and evaluating complex intervention guidelines* (MRC 2008). The first phase of the method was to develop an occupational therapy intervention specification for this study; as this did not exist with good utility. This process was reported using the *CReDICI* to ensure transparent reporting of its development (Mohler et al 2012) (see Chapter four). A task analysis approach was applied to extrapolate occupational therapy theory, practice and outcomes (Gitlin 2013). This was generated from research and practice evidence bases and included consultation with stakeholders. The Intervention specification was utilised in the second phase of the method which was a feasibility study; it was found to capture 98% of occupational therapy practice. The feasibility study was run across two centres. It was designed to test the key uncertainties in the design of a pragmatic RCT, which had been identified through carrying out the systematic review (Chapter two).

The position now is that although the feasibility study was not powered to test null hypotheses, the study outcomes are encouraging. Self-reported experience of occupational performance and satisfaction with occupational performance was found to be statistically significant *(p=.002, p=.001) (p<.05).* Self evaluated transition (SET) which rates changes in health was also statistically significant *(p=.026) (p>.05)* for the participants in the study. The COPM has been shown to be sensitive enough to detect change in self-reported experience of

occupational performance and satisfaction with occupational performance and to have utility with people with a diagnosis of psychosis. The majority of the other outcome measure scores (time use, participation restriction and satisfaction with participation) showed a positive increase and although this was not statistically significant *(p>.05),* it needs to be considered in the context of a small sample size of 14 participants. Further to this the majority of participants (n=10, 71%) agreed or strongly agreed that they were more satisfied with their participation in the activities and occupations most meaningful to them. This response together with the results from the study outcomes are promising and warrant further investigation.

7.12 Conclusion and recommendations

The study has set up the next phase of developing a complex intervention, i.e. conducting an occupational therapy pragmatic RCT, with people with a diagnosis of psychosis, living in the community. This will be with an occupational therapy intervention specification which has been evaluated and shown to be a valid description of occupational therapy, capable of capturing 98% of occupational therapy practice with participants with a diagnosis of psychosis, living in the community. Whilst it does put some additional burden on occupational therapists to complete, it has been described as being straight forward, structured and logical and has been shown to have good utility. The occupational therapy intervention specification has demonstrated its ability to meet the requirements of the *TIDiER checklist* (Hoffmann et al 2014). This will therefore strengthen the methodological quality of a future pragmatic RCT and support replication of the study. The knowledge about how occupational therapy

enables participation has been advanced through identifying core aspects of an occupational therapy intervention with people with a diagnosis of psychosis:

- Every time a person-centred contact
- Occupational needs formulation was the focal point
- Enablement to do more, be active and be more

Recommendations for a next stage study (summarised below) will also build on the learning regarding recruitment and retention of participants, including having information for a power calculation. The next stage study will have a method of monitoring and measuring fidelity and a method for adherence to therapy that has been developed and tested. An approach to measuring participation in activities of daily living was created and explored in this study; it also now requires a larger scaled study to test the potential correlations between the measurement of participation and its constructs. Considerable steps have been taken towards being able to determine the effectiveness of occupational therapy with people with a diagnosis of psychosis.

Recommendations for a pragmatic RCT

- Prior to the study, work collaboratively with the partner centres to agree and be explicit about how the main study protocol would be specifically carried out in their centre. Including having clear procedures and agreements between the researcher and all involved with regards to roles and responsibilities, how the study is monitored and how issues are identified and managed. Continue to maintain effective and regular communication with the partner centres throughout the study.
- Engagement with those who are most likely to facilitate the research in practice at the research design and development stage.

- Service user consultation regarding: method of measuring adherence, incentives/ payment for additional time taken to be part of the study and to expand conversations regarding how occupational therapy enables participation?
- Statistical analysis of the correlations between the outcome measures, with a larger sample size.
- Further exploration of the use of shadowing of a random sample of occupational therapy sessions to consider how it could strengthen the method of measuring fidelity further?
- Allow more time to recruit the target sample size; to recruit at a rate of approximately one new participant receiving therapy to the study a month, per occupational therapist. Achieve the sample size by increasing the number of centres involved in a pragmatic randomised controlled trial.
- Specify timescales on the enrolment process and the post-intervention outcome measures.
- Occupational therapists method of measuring adherence to have two separate ratings: face to face therapy session and adherence to occupational therapy plan in-between sessions.
- Include a ‘run in’ period as part of the overall study timescales, for occupational therapists to become familiar and confident with using the occupational therapy log.

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